Section 6.12.5 Annex Point IIA 6.9.5	**Diagnosis of poisoning including specific signs of poisoning and clinical tests, if available**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [...] **Limited exposure [...]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	No clinical studies are available and no human poisoning cases are known. However, exposure to thiacloprid may give rise to clinical symptoms in humans (*cf.* study summary 6.12.8).	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	09/10/2006	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	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 6.12.6 Annex Point IIA 6.9.6	Sensitisation/allergenicity observations, if available	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [...] **Limited exposure [...]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	No information on sensitisation/allergenicity is available.	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	09/10/2006	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	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 6.12.7 Annex Point IIA 6.9.7	**Specific treatment in case of an accident or poisoning: first auf measured, antidotes and medical treatment, if known**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [...] **Limited exposure [...]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	A specific antidote has not been investigated. In case of an oral uptake, first aid measures should consist of removal of ingested compound by gastric lavage or induction of vomiting and symptomatic treatment. Contaminated skin should be washed immediately with plenty of water.	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	09/10/2006	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	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 6.12.8 Annex Point IIA 6.9.8	Prognosis following poisoning	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [...]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [...]	**Other justification** [X]	
Detailed justification:	From the acute oral toxicity studies in rats, possible clinical signs in humans exposed to high doses would include tremor, constipation, decreased motility and reactivity, poor reflexes, spastic gait, spasmodic state, convulsions, tachypnea, dyspnea, diarrhea or increased salivation. The duration and severity of these signs would depend on the extent and route of exposure. Laboratory studies in animals indicate that recovery from thiacloprid-induced acute symptoms could be expected within a couple of days of exposure.	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	09/10/2006	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	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 6.14 / 6.16 Annex Point IIIA 6.3/.5 and 11.2	**Other tests related to humans / any other tests relating to human exposure of the active in the proposed biocidal products**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [...] **Limited exposure [...]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	Additional tests related to the exposure of the active substance to humans are not considered to be necessary for the purpose of performing a reliable human health risk assessment in the context of the use of the active in wood preservatives.	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	09/10/2006	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	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 6.15.1 - 6.15.6 Annex Point IIIA 11.1.1 - 11.1.9	Residues in Food and Feedstuffs	
	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 Lanxess recommendations for the application of wood preservatives, wood preservatives must not be applied to wood which is likely to come into prolonged contact with the skin or to wood which comes into direct contact with foodstuffs. (e.g.: Preventol A5-S, Product Information). The claimed label for the thiacloprid guide recipes also contains the instruction: "Do not apply to wood which is likely to come into prolonged contact with the skin or to wood which comes into direct contact with foodstuffs". Due to the non-intended exposure to food and feedstuffs it is justified not to submit data on residues in food and feedstuffs in the scope of the BPD submission as active in wood preservatives.	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	09/10/2006	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	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 6.17 Annex Point IIIA, VI.6	Toxic effects of metabolites in plants	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [...] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	The active thiacloprid is used as a insecticide in wood preservation and not on plants in the scope of the EU BPD dossier. Residues of metabolites in eatable plants will not occur from the biocidal application as wood preservative. Therefore Point 6.17 does not apply and it is justified not to submit data on this point.	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	09/10/2006	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	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 A7.1.1.1.1
Annex Point IIA7.6.2.1

Hydrolysis as a function of pH and identification of breakdown products

			Official use only
		1 REFERENCE	
1.1	**Reference**	Brumhard, B. (1998a): Hydrolysis of YRC 2894 in sterile aqueous buffer solutions. Bayer AG, Report No. PF4338, date: 1998-02-16. *PPP-Monograph Chapter: B.8.4 Fate and behaviour in water. B.8.4.1 Aqueous hydrolysis*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; US-EPA guideline (Pesticide Assessment Guidelines, Subdivision N, Series 161-1).	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	X
		3 MATERIALS AND METHODS	
		The rate of hydrolysis of YRC 2894 (thiacloprid) was investigated by the addition of [14C]YRC 2894 to separate samples of sterile aqueous 0.01M buffer solutions (pH 5, 7 and 9; ca. 0.35 mg a.s./litre). Samples (5 ml) of each treated buffer were then incubated at 25 ± 1°C for 30 days in the dark in vials without traps for volatiles. Duplicate samples were taken for analysis at 0, 2, 7, 13, 20, 27 and 30 days after application for all three treatments. Radioactivity was quantified by LSC and identified by TLC.	X
		4 RESULTS	
		Recoveries were 99-105% AR for all treatments. YRC 2894 was recovered at constant levels (94-103% AR) throughout the experiment duration across all three treatments. No formation of degradation products was observed for pH 5 and 7 at any time of sampling. Two minor hydrolysis products accounting for <2% AR were detected at pH 9.	

Section A7.1.1.1.1 **Hydrolysis as a function of pH and identification of breakdown products**

Annex Point IIA7.6.2.1

5 CONCLUSION

5.1	**Conclusion**	YRC 2894 was thus considered hydrolytically stable at pH 5, 7 and 9. No formation of degradation products was observed for pH 5 and 7 at any time of sampling. Two minor hydrolysis products accounting for <2% AR were detected at pH 9.	X
		[redacted]	
5.1.1	Reliability	[redacted]	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	6/7/2006
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.1.1.1.2
Annex Point IIA7.6.2.2

Phototransformation in water including identity of the products of transformation (1)

			Official use only
		1 REFERENCE	
1.1	**Reference**	Henneböle, J. and Bornatsch, W. (1998): Photolysis of YRC 2894 in aqueous buffer solution. Bayer AG, Report No. PF4330, date: 1998-02-18. *PPP-Monograph Chapter: B.8.4 Fate and behaviour in water. B.8.4.2 Aqueous photolysis (Study 1)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, US-EPA (Pesticide Assessment Guidelines, Subdivision N, Series 161-2) and SETAC guidelines	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		A sterile aqueous buffer solution (pH 7) containing [14C]YRC 2894 (thiacloprid) at a concentration of 0.385 mg a.s./l was prepared. Aliquots (5 ml) were incubated at 24.3 ± 1°C in rectangular glass vessels (surface of exposed solution 15 cm2) each closed with a glass stopper, but not fitted with traps. Replicate vessels were either kept in the dark or exposed to a xenon lamp (Suntest unit; continuous irradiation at an average of 9.45×10-3 W/cm2; >290 nm) for up to 18 days. There was a small overlap between the UV absorption spectrum of YRC 2894 and the spectral range of the filtered xenon light, but this was considered minimal. Duplicate illuminated samples were taken for analysis after 0, 1, 4, 7, 11, 15 and 18 days. Duplicate dark controls were taken after 18 days only. Radioactivity in each buffer sample was quantified by LSC and characterised by TLC and HPLC. Identification of metabolites was performed using MS- and NMR-spectroscopy.	X
		4 RESULTS	

Section A7.1.1.1.2 Phototransformation in water including identity of the products of transformation (1)

Annex Point IIA7.6.2.2

Total recovery was 101-107% AR. YRC 2894 was degraded throughout the course of the experiment in illuminated samples only and accounted for 84% AR after 18 days of irradiation. A minor photoproduct accounting for a maximum of 5.4% AR (day 18) was identified as M35.

The mean DT_{50} of YRC 2894 was calculated as 79.7 days continuous irradiation (equivalent to 324 solar summer days for Phoenix, Arizona, USA) for illuminated samples (r^2=0.91). No degradation of YRC 2894 was observed in the dark controls.

5 CONCLUSION

5.1 Conclusion X

In aqueous solution thicaloprid photodegrades slowly under environmentally relevant pH- and temperature conditions (DT_{50} = 79.7 days). This is equivalent to 324 solar summer days for Phoenix, Arizona, USA (40°N, similar light intensity for the southern European regions).

After 18 days of irradiation a minor photoproduct accounting for a maximum of 5.4% AR was identified as M35.

[redacted]

5.1.1 Reliability [redacted] X

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 6/7/2006

Materials and Methods [redacted]

Results and discussion [redacted]

Conclusion [redacted]

Reliability [redacted]

Acceptability [redacted]

Remarks [redacted]

COMMENTS FROM ...

Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.1.1.1.2
Annex Point IIA7.6.2.2

Phototransformation in water including identity of the products of transformation (2)

			Official use only
		1 REFERENCE	
1.1	**Reference**	Hellpointner (1995a): Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation of YRC 2894 in water. Bayer AG, Report No. PF4083, date: 1995-03-01. *PPP-Monograph Chapter: B.8.4 Fate and behaviour in water. B.8.4.2 Aqueous photolysis (Study 2)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, ECETOC guidelines (Test Guideline "Phototransformation of chemicals in water, Part A: Direct phototransformation, UBA).	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		Non-radiolabelled YRC 2894 (thiacloprid) solutions (3 ml) in water (two separate experiments with concentrations of 5.14 mg a.s./litre or 5.35 mg a.s/litre) were exposed to artificial polychromatic light in a merry-go-round irradiation apparatus (mercury immersion lamp TQ150 from Original Hanau Co. fitted with Duran 50 filter) at 25°C for a maximum of 500 minutes. Separate samples were removed at intervals of 35 to 65 minutes and analysed by HPLC using external standards. Calculations of the quantum yield were performed using the software QUANT and environmental half-lives were derived using two arithmetic models (GC-SOLAR and the model of Frank and Klöpffer). An additional test not part of the protocol was carried out using the before-mentioned equipment (but without using a solvent) to assess the photodegradation of YRC 2894 on quartz glass surfaces.	X

Section A7.1.1.1.2
Annex Point IIA7.6.2.2

Phototransformation in water including identity of the products of transformation (2)

4 RESULTS

The UV-absorption spectrum of YRC 2894 in water was independent of pH and showed a peak at 241-242 nm and a small shoulder of absorption at about 222 nm. The absorption in the >290 nm range was very limited and terminated at about 305 nm.

No degradation of YRC 2894 was observed during the irradiation period of 500 minutes and no photoproducts were detected. The mean quantum yield of the direct photodegradation of YRC 2894 in water as calculated from the UV-Vis absorption and degradation kinetics was Φ = 0.000352. Environmental half-lives for all scenarios considered (different seasons and latitudes) were predicted to be >1000 days. The extrapolated experimental half-life of YRC 2894 on the glass surface was 1244 min.

5 CONCLUSION

5.1 Conclusion

Environmental half-lives for all scenarios considered (different seasons and latitudes) were predicted to be >1000 days. The extrapolated experimental half-life of YRC 2894 on the glass surface was 1244 min. X

[redacted]

5.1.1 Reliability [redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	11/07/2006
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.1.1.2.1 Biodegradability (ready)

Annex Point IIA7.6.1.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	Reis, K-H. (2005): Ready biodegradability of Thiacloprid in a Manometric Respirometry Test. Report No. 23252160. Sponsored by LANXESS Deutschland GmbH. Test facility: IBACON GmbH, date: 2005-07-18. *Not included in the PPP-Monograph. Test was performed as a requirement of the biocide products directive.*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; OECD guideline 301F, Directive 92/69/EEC method C.4-D	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
3.1	**Test material**	Thiacloprid	
3.1.1	Lot/Batch number	Batch No. [redacted]	
3.1.2	Specification	As given in section 2 of dossier	
3.1.3	Purity	[redacted]	
3.1.4	Further relevant properties	Water solubility of thiacloprid: about 0.185 g/l at 20°C ([redacted] 1996)	
3.1.5	Composition of Product	-	
3.1.6	TS inhibitory to microorganisms	Result of the respiration inhibition test with activated sludge according to ISO 8192: EC_{50} = 6330 mg/l; Reference: Mueller, G. (1995): Studies on the ecological behaviour of YRC 2894. Bayer AG, Institute for Environmental Analyses, Leverkusen, Germany, Report No. 544A/95, date: 1995-09-21.	
3.1.7	Specific chemical analysis	There was no specific chemical analysis conducted in addition to the DOC measurement during the study.	X
3.2	**Reference substance**	Yes, Aniline (Purity: 99.5 %)	
3.2.1	Initial concentration	102.87 mg/l	

	of reference substance	
3.3	**Testing procedure**	
3.3.1	Inoculum / test species	Test organism was a mixed population of aquatic micro-organisms (activated sludge). Origin: domestic waste water treatment plant from the sewage plant Groß-Zimmern, Germany. Sludge was separated by centrifugation. Sludge suspension was aerated before use.
3.3.2	Test system	The test was performed in test flasks. The BOD determination was performed using a BOD-sensor system Aqualytic (63231 Neu Isenburg, Germany)
3.3.3	Test conditions	Flask 1, 2: Inoculum + Test substance; Flask 3, 4: Blank inoculum (without test substance); Flask 5: Reference substance Aniline + Inoculum Flask 6: Abiotic control Flask 7: Toxicity control (Test substance + Aniline + Inoculum). Each test flask is inoculated with 30 mg activated sludge per 244 ml medium. The mixtures were continuously stirred in the dark at 21.5-21.6 °C.
3.3.4	Method of preparation of test solution	10 mL of stock solution A and 1mL of the stock solution B-D were combined and filled to a final volume of 1000 mL with deionised water. See the composition of every single solution A-D in Table A7_1_1_2-3
3.3.5	Initial TS concentration	ca. 102 mg/l
3.3.6	Duration of test	28 days
3.3.7	Analytical parameter	BOD (biological oxygen demand)
3.3.8	Sampling	Degradation was followed by BOD determinations each day
3.3.9	Intermediates/ degradation products	Not identified
3.3.10	Nitrate/nitrite measurement	No
3.3.11	Controls	Control without test substance, toxicity and abiotic control
3.3.12	Statistics	The degree of biodegradation is calculated by expressing the concentration of the oxygen uptake (corrected for that in the blank inoculum control) as a percentage of the theoretical oxygen demand.
		4 RESULTS
4.1	**Degradation of test substance**	
4.1.1	Graph	Provided in the report

X

Section A7.1.1.2.1 Biodegradability (ready)

Annex Point IIA7.6.1.1

4.1.2	Degradation	0 % degradation after 28 days
4.1.3	Other observations	No
4.1.4	Degradation of TS in abiotic control	The oxygen demand was zero
4.1.5	Degradation of reference substance	A degradation of 103 % was achieved for Aniline within 14 days
4.1.6	Intermediates/ degradation products	Not applicable

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The study was designed to assess the ready biodegradability of thiacloprid and was conducted according to OECD guideline 301F and the Council Directive 92/69/EEC, method C.4-D. A solution of the test substance in a mineral medium was inoculated and incubated under aerobic conditions in the dark at 21.5-21.6 °C. Degradation was followed by BOD determinations each day. The study shows no deviations from the guideline.
5.2	**Results and discussion**	Thiacloprid showed 0 % degradation after 28 days. A degradation of 103 % was achieved for the reference substance Aniline within 14 days. The used concentrations of the test substance did not show significantly toxic effects to bacteria (toxicity control).
5.3	**Conclusion**	The validity criteria can be considered as fulfilled. Thiacloprid has to be classified as "Not Readily Biodegradable".
5.3.1	Reliability	[redacted] X
5.3.2	Deficiencies	GLP guideline study acceptable for assessment.

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	07/07/2006
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_1_1_2-1: Inoculum / Test organism

Criteria	Details
Nature	activated sludge
Species	not specified
Strain	not specified
Source	Activated sludge plant treating predominantly domestic waste water
Sampling site	Groß-Zimmern plant, Germany
Laboratory culture	No
Method of cultivation	not specified
Preparation of inoculum for exposure	1.5 g dry material /L suspension was prepared by centrifugation
Pretreatment	No adaptation; sludge suspension was aerated before use
Initial cell concentration	30 mg sludge / 244 ml medium based on dry weight (i.e. ca. 123 mg/l)

Table A7_1_1_2-2: Test system

Criteria	Details
Culturing apparatus	Respirometer
Number of culture flasks/concentration	2
Aeration device	Yes; not specified
Measuring equipment	BOD-sensor system Aqualytic (63231 Neu Isenburg, Germany)
Test performed in closed vessels due to significant volatility of TS	No

Table A7_1_1_2-3: Test conditions

Criteria	Details
Composition of medium	10 mL of solution A and 1 mL of solutions B, C, and D were added to 1 L deionised water. A: 8.5 g KH_2PO_4 / L 21.75 g K2HPO$_4$ / L 33.4 g $Na_2HPO_4*2H_2O$ / L 0.5 g NH_4Cl B: 22.5 g $MgSO_4*7H_2O$ in 1 L distilled water C: 36.4 g $CaCl_2$ per 1 L distilled water D: 0.25 g $FeCl_3$ in 1 L distilled water
Additional substrate	No
Test temperature	21.5-21.6 °C
pH	7.6 at the start and 7.6-7.9 at the end of test
Aeration of dilution water	No
Suspended solids concentration	30 mg activated sludge / 244 mL based on dry weight
Other relevant citeria	Continuous stirring of test solution; CO_2 was absorbed in an aqueous solution 45 % of KOH

Section 7.1.1.2 Annex Point IIA 7.6.1.2	**Inherent biodegradability, where appropriate**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [...]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ].**	
Detailed justification:	OECD tests on inherent biodegradability on thiacloprid were not performed because higher tiered studies on behaviour of the test substance in water-sediment systems are available.	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	07/07/2006	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	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 7.1.1.2.3 Annex Point IIIA 12.2	Biodegradation in seawater	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure** [X]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification** [X].	
Detailed justification:	For thiacloprid used as an active in wood preservatives JJT 3968 (0.02 % thiacloprid) and JJT 3947 (0.5 % thiacloprid) is not claimed. Therefore a test on biodegradation in seawater was not performed.	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	07/07/2006	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	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 7.1.2.1.1 Annex Point IIIA 12.2	**Aerobic biodegradation with respect to biological sewage treatment**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [X].	
Detailed justification:	A test on aerobic biodegradation with regard to the sewage treatment plant is not required for actives used in wood preservatives.	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	07/07/2006	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	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 7.1.2.1.2 Annex Point IIIA 12.2	Anaerobic biodegradation	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [...]	Technically not feasible [ ] Scientifically unjustified [ ] Other justification [X].	
Detailed justification:	A test on anaerobic biodegradation with regard to the sewage treatment plant is not required for actives used in wood preservatives.	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	07/07/2006	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	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 7.1.2.2.1 Annex Point IIIA 12.2	Aerobic aquatic degradation study	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] Limited exposure [...]	Technically not feasible [ ] Scientifically unjustified [ ] Other justification [ ].	
Detailed justification:	A test on aerobic biodegradation in water is not submitted because studies on water sediment systems are available for thiacloprid.	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	07/07/2006	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	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 A7.1.2.2.2 Water/sediment degradation study (1)

Annex Point IIIA XII2.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	Riegner, K. (1997 *[Monograph: 1997b]*): Aerobic aquatic degradation and metabolism of YRC 2894 in the water-sediment system Bayer AG, Report No. PF4273 (MR-622/97), date: 1997-12-09. *PPP-Monograph Chapter: B.8.4. Fate and behaviour in water. B.8.4.4 Water/sediment studies (Study 1)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; German BBA (Part IV, 5-1) and SETAC guidelines.	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		Samples of untreated Hönniger pond water (artificially dammed pond in Germany; pH 7.2) and associated sandy silt loam sediment (pH 6.0; 3.8% oc), and Lienden lake water (lake in an agricultural area, the Netherlands; pH 8.3) and associated sand sediment (pH 8.4; 0.39% oc) were equilibrated in flasks for 18 days (50 g sediment dry weight, sieved to 2 mm; water/sediment ratio of 9/1 (w/w)). Following equilibration, [14C]YRC 2894 (thiacloprid) (ca. 0.120 mg a.s./litre, corresponding to an application rate of ca. 360 g a.s./ha when considering a water body of 30-cm depth) was added in acetonitrile to 18 flasks for each system. All treated flasks were fitted with traps for CO_2 (soda lime) and organic volatiles (polyurethane plug). All flasks were then incubated at 20 ± 1°C in the dark for up to 100 days under aerobic conditions.	X
		Duplicate treated flasks were analysed at day 0, 1, 3, 7, 14 35, 62 and 100 days of incubation. The water was decanted and radioactivity was quantified by LSC and identified by TLC and HPLC against authentic samples. The moist sediment was extracted three times with acetonitrile and then with dichloromethane. Radioactivity from the extracts was quantified by LSC and identified by TLC and HPLC against authentic samples. Aggravated (Soxhlet with acetonitrile, temperature not specified) and further extraction (Soxhlet with methanol and HCl) steps on dried sediment were carried out for the Hönniger samples. Remaining radioactivity not extracted from sediment was quantified by combustion analysis and LSC. Radioactivity in the volatile traps was	

quantified by LSC. Respiration rate, pH, redox potential in the supernatants and sediment, and oxygen contents were monitored.

For both systems, redox potential (water) was 145 to 255 mV. Redox potential for the sediment ranged from 140 to 213 mV for the Lienden system and from –126 to 90 mV for the Hönniger system. Negative values were attributed to the difficulty in measuring redox potential in thin layers of sediments and to a possible lack of oxygen in the sediments.

4 RESULTS

Non-extractable residues increased to 22% AR and 17% AR after 100 d for the Hönniger system and Lienden system, respectively, whilst CO_2 increased to 4% at the end of the study for both systems. No organic volatiles other than CO_2 were detected. X

Radioactivity in the supernatant water attributed to YRC 2894 decreased rapidly and values of <2% AR were detected after 35 days of incubation (YRC 2894 was not detectable after 100 days). YRC 2894 partitioned between water and sediment (Table A7_1_2_2_2-1) and degraded to form one major metabolite (M02), one minor metabolite (M30, maximum of 9.5% RA) and one unknown minor metabolite. The metabolites M02 and M30 were predominantly found in the aqueous phase in Lienden samples, but were more equally distributed between water and sediment in the Hönniger samples. At study termination, M02 accounted for 8 and 50% AR for Hönniger and Lienden water samples, respectively, and for 32.9% AR and 6.4% AR for sediment samples for the two systems, respectively.

Degradation rates for YRC 2894 were calculated by the applicant according to first-order kinetics using curve fitting software (Table B.8.28). Rates were recalculated using linear regression also assuming first-order kinetics (Table A7_1_2_2_2-2). The significant difference between the two techniques in the values for the Hönniger pond (water only) mainly results from the fact that zero values (concentrations at day 62 and 100) were not included in the linear regression.

Degradation of YRC 2894 was concluded to proceed via M02 to M30 with the potential for formation of CO_2 and bound residues from all three compounds.

5 CONCLUSION

5.1 Conclusion

Degradation of YRC 2894 in the water/sediment system (DT_{50} = 10.7 - 27.9 days) proceeds via M02 to M30 with the potential for formation of CO_2 and bound residues from all three compounds. YRC 2894 was quickly eliminated from the water body (DT_{50} = 2.9 – 10.8 days). X

[redacted]

Section A7.1.2.2.2 Water/sediment degradation study (1)

Annex Point IIIA XII2.1

5.1.1 Reliability [redacted] X

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	21/11/2006
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_1_2_2_2-1 Concentrations of YRC 2894 (thiacloprid) and its significant metabolites in water and sediment samples

	Hönniger				Lienden			
	Water		Sediment		Water		Sediment	
	Max (%AR)	Peak (day)	Max (%AR)	Peak (day)	Max (%AR)	Peak (day)	Max (%AR)	Peak (day)
YRC 2894	■	■	■	▮	■	■	■	■
M02	■	▮	■	▮	■	▮	■	■
M30	■	■	■	■	■	■	■	■
Unknown metabolite	■	■	■	■	■	■	■	▮

Table A7_1_2_2_2-2 First-order dissipation rates for YRC 2894 (thiacloprid)

	First-order kinetics by linear regression			First-order kinetics by curve fitting		
	DT_{50} (days)	DT_{90} (days)	r^2	DT_{50} (days)	DT_{90} (days)	r^2
HÖNNIGER POND						
whole system	■	■	■	■	■	■
water	■	■	■	■	■	■
LIENDEN LAKE						
whole system	■	■	■	■	■	■
water	■	■	■	■	■	■

Section A7.1.2.2.2 Water/sediment degradation study (2)

Annex Point IIIA XII2.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	Fritz, R. (1998): Anaerobic aquatic metabolism of the active ingredient YRC 2894. Bayer AG, Report No. PF4352, date: 1998-03-23. *PPP-Monograph Chapter: B.8.4. Fate and behaviour in water. B.8.4.4 Water/sediment studies (Study 2)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; US-EPA guidelines (Pesticide Assessment Guidelines, Subdivision N, Series 162-3: mainly anaerobic).	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		Samples of water (pH not reported) and associated silty clay loam sediment (USDA classification; pH 8.0; 1.2% oc) from a pond located on a research farm in Stilwell (Kansas, USA) were amended with sucrose and equilibrated anaerobically (ca. 400 ml water and 50 g dry weight sediment; 2 mm sieved) for 30 to 112 days at 20°C in the dark in flasks fitted with a bubble counter attachment or with a device that enables a flow of nitrogen. Following equilibration, [14C]YRC 2894 (thiacloprid) was added at 230 µg a.s./l in methanol (Test A; assuming an application rate of 0.35 kg a.s./ha, a water sediment depth of 15 cm and a density of 1 kg/dm3) and at a lower application rate (Tests B and C; 0.175 mg a.s./l, assuming a water depth of 200 cm). Test C resulted from the failure of the incubation system to maintain anaerobic conditions. All incubation vessels were fitted with flow-through systems with nitrogen (for test A, this system replaced a closeable wash bottle connected with an air sample bag after 85 days) and trap attachments for CO_2 (soda lime) and other organic volatiles (polyurethane foam). Treated flasks were incubated in the dark at 20 ± 1°C for up to 360 days under anaerobic conditions. Dissolved oxygen content, redox potential and pH were measured at each sampling point. Duplicate flasks were analysed at day 0, 3, 7, 14, 29, 59, 120, 251 and 360 days after treatment for test A, at 0, 29, 60, 250 and 360 days for test B, and at 0, 120, 251 and 360 days for test C. Sterile samples were analysed at 59 (test A), 60 (test B) and 120 days (test C) after the beginning of the incubation. Radioactivity from the supernatant water	X

was quantified by LSC and identified by TLC using reference samples (the samples for 250 and 360 days for test B were initially extracted by SPE). Radioactivity in sediment samples was extracted (water, methanol/water, methanol), quantified by LSC and identified by TLC and HPLC or TLC after concentration, where appropriate. Radioactivity in the extracted sediment was quantified by combustion analysis. Also, an aggravated extraction (methanol/water 50/50 under reflux for ca. 3 hours) was carried out before analysis of extracts by LSC and TLC. Water phases from the 14-day samples were purified and analysed by MS for structure elucidation. Radioactivity in volatile traps was quantified by LSC.

4 RESULTS

Results for test C are considered most reliable because anaerobicity was compromised in tests A and B. X

Total recovery for test C was 93-99% AR. Redox and dissolved oxygen measurements confirmed that anaerobicity was kept throughout the experiment. YRC 2894 declined slowly from day 0 (87% AR) to day 360 (69% AR). The compound was stable under sterile conditions (87 to 91% AR at day 360) and the metabolic behaviour was similar to non-sterile conditions. At least six metabolites were detected, but only the amide M02 accounted for >10% AR (14% AR at day 360). The minor metabolites M29 and the sulfonic acid M30 were only detected at day 251. DT_{50} as calculated from the data using first-order kinetics was 1041 days.

Anaerobicity was compromised for tests A and B as shown by positive redox values and oxygen content measurements. Change of the incubation system at day 85 for test A did not result in an improvement in anaerobic conditions for the rest of the study period. The aerobicity detected on day 250 for test B was attributed to a mucous secretion of bacterial origin and its removal led to the recovery of anaerobic conditions. The two tests were nevertheless maintained since it was considered that test A would provide information on the influence of aerobicity/anaerobicity on the metabolism and degradation kinetics of YRC 2894 and that anaerobic conditions were kept for at least 2 months in test B.

Total recovery for the two tests was 90 to 104% AR. Maximum levels of volatile compounds (including CO_2) were 0.3% and 2.2% for tests A and B, respectively. The radioactivity in the water samples decreased in both studies to reach ca. 21% for test A and ca. 12% for test B. Bound residues accounted for a maximum of ca. 20% AR for both tests. As for test C, YRC 2894 concentrations decreased over time but the final concentrations at day 360 were much lower under pseudo-aerobic conditions (35% for test A and 37% for test B). M02 was the only metabolite produced at >10% AR (12% at day 360 for test A, 38.5% AR at day 250 and 21% at day 360 for test B).

DT_{50} values for YRC 2894 calculated from the data using first-order kinetics were 392 days and 302 days for test A and B, respectively.

Section A7.1.2.2.2 Water/sediment degradation study (2)

Annex Point IIIA XII2.1

5 CONCLUSION

5.1 Conclusion

The observed faster degradation kinetics for tests A and B (DT_{50} = 302-392 days) compared to test C were attributed to the aerobic conditions which developed during the third study. Thus, under anaerob conditions thiacloprid experiments slower degradation (DT_{50} = 1041 days). Major metabolite was M02.

X

[redacted]

5.1.1 Reliability

[redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26/07/2006
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.1.2.2.2 Water/sediment degradation study (3)

Annex Point IIIA XII2.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	Heimbach, F (1997a *[Monograph: 1997d]*): Biological effects and fate of YRC 2894 SC 480 in outdoor microcosm ponds. Bayer AG, Report No. HBF/Bt 01, date: 1997-03-21. Methods of analysis here cited are outlined in the study summaries from chapter 4. *PPP-Monograph Chapter: B.8.4. Fate and behaviour in water. B.8.4.5 Aquatic dissipation in the field*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No; Test procedure similar to standard test guidelines. Test conducted in the scope of a microcosm study (*cf.* study summary 7.4.3).	X
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		YRC 2894 SC 480 (containing [redacted] w/w a.i.) was applied two times at 14 days interval onto the water surface of nine test ponds in Germany. The microcosm consisted of cylindrical black plastic tanks (diameter 2.75 m, 1.55 m in depth; surface area 5.94 m2). Tanks were filled to a nominal level of 1 m of water and hence contained 6.0 m3 of water. The sediment layer in the base was 12 cm deep (silty sand, 1.1 % oc, CEC 5 meq/100g). Tanks were initially interconnected with an additional tank and water pumped between them to allow the physical, chemical and biological parameters to stabilise prior to the start of the study. Just prior to application of the first treatment tanks were isolated from each other. Tanks were sunk into the ground to the depth of the water surface. The tanks were outside and exposed to climatic conditions. There was no replication of the treatments.	X
		The nine treatment levels corresponded to 0.32, 0.56, 1.0, 1.8, 3.2, 5.6, 10, 18 and 32 µg a.s./L per application. In addition three further tanks were kept as untreated controls. The test substance was applied at the beginning of the early growing season in May 1996 on day 0 and day 14. Applications were sprayed on to the water surface. It was confirmed through measurement of residue remaining in the sprayer that 99.7 and 99.6% of the target dose was applied on day 0 and 14 respectively. The ponds were investigated for a period of 98 days after	

the first treatment.

Samples were taken at four pre-determined positions in the tank. Water was sampled by suction, withdrawing approximately 7 l of water. Sediment samples were taken using a grab into the top 5 cm.

The chemical oxygen demand (COD) concentrations fluctuated between microcosms during the pre-treatment period. Between day 49 and 77 the COD of most of the treatment ponds was below the control, possibly due to lower algae densities. A dose related effect at the higher doses of YRC 2894 cannot be excluded.

Oxygen content, pH and temperature were measured 2-3 times per week. The monthly mean temperature during the test period was 12 to 18 °C. The temperature in the pond water varied between 11 to 26 °C with no real difference between the tanks. The oxygen content varied between 9 and 17 mg/l. There were some differences in oxygen levels between the control and some of the treatments during the course of the study. However, these were considered to be within the range of natural fluctuation and no dose response relationship was apparent.

4 RESULTS

During the pre-treatment period the pH values corresponded well between all the microcosms. After the first treatment there were some small differences between the treatments and the controls. However, there was no dose response relationship and differences were a maximum of 0.5 of a unit. It was therefore considered that 'YRC 2894 SC 480' did not influence the pH of the microcosm. The pH during the study was 8 - 10. No dose related effect of 'YRC 2894 SC 480' on the level of nutrients (ammonium, nitrate, nitrite and phosphate) was observed during the study. Data for conductivity, carbonate hardness (calcium carbonate equivalents) and alkaline earth's (oxides of the periodic table group II elements) corresponded well between the microcosms and there did not appear to be a treatment related effect on these parameters. X

There appeared to be no direct effects of YRC 2894 on the chemical and physical parameters in the microcosm. There was some difference between the control and treatment levels 3.2 – 32 µg a.s./l during the second half of the study. This may have been caused by indirect effects of different plankton communities, as well as different development in the isolated microcosms.

The amount of YRC 2894 present in water was analysed 15 times during the course of the study. In addition the stock solutions were analysed for dose confirmation purposes. Two methods of analysis were used with the limit of quantification (LOQ) being 0.05 µg a.s./l for the test concentrations 0.32 to 3.2 µg a.s./l where solid phase extraction was utilised before HPLC-UV (Konig 1995, and Sommer 1999) and 1.0 µg a.s./l for the test concentrations 3.2 to 32 µg a.s./l where analysis was by direct injection onto HPLC-UV (modified (larger injection volume, lower LOQ) from Konig 1994). The stock solutions were on average 99.7% of nominal (range 97-104%). Two days after the first application

the concentrations ranged between 79.7 and 95.3% of the nominal concentrations. At day 16 (two days after the second application) the majority of concentrations were 74.4 – 85% of the nominal (as calculated by summing the individual nominal concentrations from a single application). It should be noted that after the second application the microcosms were exposed to concentrations in excess of the initial nominal concentrations for a period of approximately 28 days.

There was one low result at day 16, 5.6 µg a.s./l treatment with only 44.5% of the nominal concentration being detected. However, at day 28 the value was 68.4% of the nominal value and more in line with the results for the other concentrations at this time. Levels in the water continued to decline throughout the study period with only between 8-23% of the original nominal concentrations being detected on day 98. The first order DT_{50} in the water phase estimated from initial concentrations 2 days after the second treatment were 26-46 days, mean 31 days (r^2=0.82-1, n=9).

The content of YRC 2894 and its metabolite M02 in the sediment was analysed 11 times during the study period by HPLC-UV following extraction with acidified methanol water (Sommer 1997c) from the 10, 18 and 32 µg a.s./l treatments. The LOQ achieved during procedural validation was 3 µg a.s./kg dry weight sediment. The procedural recoveries during the study were 66-76 % for YRC 2894 and 56-72 % for M02. The maximum concentration of YRC 2894 in the sediment was detected on day 42 when concentrations were 28, 49 and 60 µg a.s./kg dry weight sediment in the 10, 18 and 32 µg a.s./l treatments respectively. This represents 141, 136 and 94 % of the nominal water concentrations (as calculated by summing the individual nominal concentrations from a single application) respectively. Concentrations of the metabolite M02 in the sediment were first detected 14 days after the second application. The maximum amount of M02 was detected on day 98 accounting for 9-18 µg a.s./kg dry weight sediment. This represents 62-89 % of the nominal YRC 2894 water concentrations (as calculated by summing the individual nominal concentrations from a single application). For YRC 2894 the first order DT_{50} in the sediment phase estimated from initial concentrations 28 days after the second treatment (4 data points) was 62 days, (r^2=0.82, n=1).

5 CONCLUSION

5.1 Conclusion

A thiacloprid-containing formulation (plant protection product) YRC 2894 SC 480 (a.i [redacted] v/w) was applied in a water-sediment test system. The half-life of thiacloprid in water was of approx. 31 days. The DT_{50} of thiacloprid in the sediment phase was 62 days. The main metabolite was M02 that achieved the maximum amount in sediment on day 98. X

[redacted]

Section A7.1.2.2.2 Water/sediment degradation study (3)

Annex Point IIIA XII2.1

5.1.1 Reliability [redacted]

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 27/07/2006

Materials and Methods

[redacted]

Results and discussion

Reported as in the monograph for the Plant Protection Products Directive with the [redacted]

[redacted]

Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.1.3 Annex Point IIIA XII.2.2	Adsorption / Desorption screening test	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [...]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ].**	
Detailed justification:	A screening test on adsorption is not submitted because studies on adsorption in different soil types were conducted for thiacloprid and its metabolites.	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	10/08/2006	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	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 7.1.4.1 Annex Point IIIA XII.2.2	**Field study on accumulation in sediment**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [...]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ].**	
Detailed justification:	An additional study on accumulation in sediment was not performed as this was not triggered in accordance with the Technical Notes for Guidance on Data Requirements, which states that such a study is required; - if non-extractable residues are formed exceeding 70 % of the initial dose, or - if the mineralisation rate in the water/sediment system is < 5 % in 100 d. In the available laboratory studies the amount of non-extractable residues was significantly < 70 % (22 % in pond system and 17 % in lake system). The mineralisation was below 5 % in 100 d but only by a small margin (~ 4 % in both systems).	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	07/01/2008	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	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 A7.2.1 Aerobic degradation in soil, initial study

Annex Point: IIIA XII 1.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	Fritz, R. and Bornatsch W. (1998): Degradation and metabolism of [^{14}C]YRC 2894 in soils under aerobic conditions. Bayer AG, Report No. PF4332 (MR-544/97), date: 1998-03-17. *PPP-Monograph Chapter: B.8.1 Route and rate of degradation in soil B.8.1.1 Aerobic and anaerobic studies.B.1.1.1 Soil microbial studies. B.1.1.1.2 Soil rate of degradation studies-laboratory (Study 1)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; German BBA (Part IV, 4-1) and US-EPA (Pesticide Assessment Guidelines Subdivision N, Series 162-1) guidelines.	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		Route and rate of degradation of YRC 2894 (thiacloprid) was investigated using soil 'Howe' (Indiana, US, top 15 cm; sandy loam; pH 6.7, 1.12% oc) and rate of degradation was further investigated using soils 'BBA 2.1' (Jockgrim, Germany, top 30 cm; sand; pH 5.9, 0.57% oc), 'BBA 2.2' (Hanhofen, Germany, top 30 cm; loamy sand; pH 6.3 in CaCl2, 2.48% oc) and 'Höfchen' (Burscheid, Germany, top 20 cm; silt loam; pH 6.0, 2.4% oc). Soils BBA 2.1, BBA 2.2 and Howe were stored under field conditions in wooden containers under grass cover whereas soil Höfchen was taken fresh from the field. [14C]YRC 2894 in acetonitrile was added to subsamples (10 g) of the four soils (freshly sampled, gently air-dried and sieved to <2 mm). After evaporation of the solvent, the subsamples were mixed into the entire amount of soil required for the tests (resulting YRC 2894 concentration 0.371 mg a.s./kg dry soil, assuming a field application rate of 0.30-0.35 kg a.s./ha, a soil depth of 5-15 cm and a soil bulk density of 1.5 g/cm3). Treated soil samples (100 g dry weight equivalent) contained in vessels fitted with traps for CO2 and organic volatiles (containing soda lime and glass wool, respectively) were incubated aerobically at 20 ± 1°C in the dark for up to 100 days (BBA 2.1, BBA 2.2, Höfchen) or 365 days (Howe) with soil maintained at 40% WHC (BBA 2.1, BBA 2.2, Höfchen) or at 75% of 0.33 bar moisture (Howe). Additionally, 1 kg of the Howe soil was treated at a 20-fold dose rate and incubated under the same conditions to enable structure elucidation of the metabolites.	X

Section A7.2.1 Aerobic degradation in soil, initial study

Annex Point: IIIA XII 1.1

After 0, 1, 3, 8, 14, 30, 60, 100 days (BBA 2.1, BBA 2.2, Höfchen) and additionally at 120, 179, 268, and 365 days (Howe), radioactivity from single (BBA 2.1, BBA 2.2, Höfchen, except duplicate 100-day sample) or duplicate (Howe) samples was extracted by four methanol extractions followed by one water extraction, plus additional aggravated extraction with methanol/water (50/50) for about 3 hours under reflux conditions. Radioactivity was quantified by LSC and identified by TLC and HPLC against certified reference standards. Radioactivity recovered from day 0 was defined as the applied amount. Radioactivity in trapping solutions was quantified by LSC and [14]CO2 was identified by the Grignard reaction. Radioactivity of extracted soil samples and filters were determined by combustion. Samples from the Howe soil treated with a 20-fold dose rate were analysed by MS and NMR.

4 RESULTS

Total recovery of radioactivity was 92-104% AR for all samples. Mean quantification of major components (>10% AR) is shown in Figure B.8.1 for the soil Howe. Recoveries and identities for the three other soils showed similar patterns. Distribution of radioactivity after 100 days and maximum concentrations for the two major metabolites M02 and M30 are shown in Table A7_2_1-1. Volatile organic compounds were not detected at any sampling interval. All other individual metabolites accounted for <5.7% AR during the course of the incubation. Two degradation products (M33 and M03) were only found in the soil treated with the 20x dose rate. X

Degradation of YRC 2894 best fitted sqrt 1st order for soil BBA 2.1 and sqrt 1.5th order for all three other soils. DT_{50} and DT_{90} values were also calculated by the applicant using first-order kinetics with non-linear fitting (no r^2 provided). As degradation kinetics deviated strongly from first-order kinetics fitted by linear regression in three of the four soils (r^2 0.57-0.71), DT_{50} and DT_{90} values were re-calculated using a graphical method. Values are reported in Table A7_2_1-2. Large discrepancies are attributed to the use of different methods and to the fact that degradation of YRC 2894 does not follow first-order kinetics.

The proposed aerobic degradation pathway of YRC 2894 is presented in Figure A7_2_1-1.

5 CONCLUSION

5.1 Conclusion

In soil YRC 2894 was thoroughly metabolised and rapidly degraded to $^{14}CO_2$ under aerobic conditions. The experimental disappearance time (DT_{50}) was estimated by evaluation of the degradation curves to be ≤ 3 days for all soils. X

Since two metabolites (M02, M30) occurred above 10 % of the applied radioactivity, additional investigations were conducted to describe their degradational behaviour in soil. The amide derivative of YRC 2894 (M02) was the main metabolite in all soils investigated.

Based on the above-mentioned results and assuming that a decrease in

temperature of 10°C will multiply the half-lives with a factor of 2.2, it can be assumed that the resulting half-lives at 10°C would still be far below 90 days.

[redacted]

5.1.1 Reliability [redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26/07/2006
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_2_1-1 **Distribution of radioactivity at day 100 and maximum concentrations of M02 and M30 in the four soils**

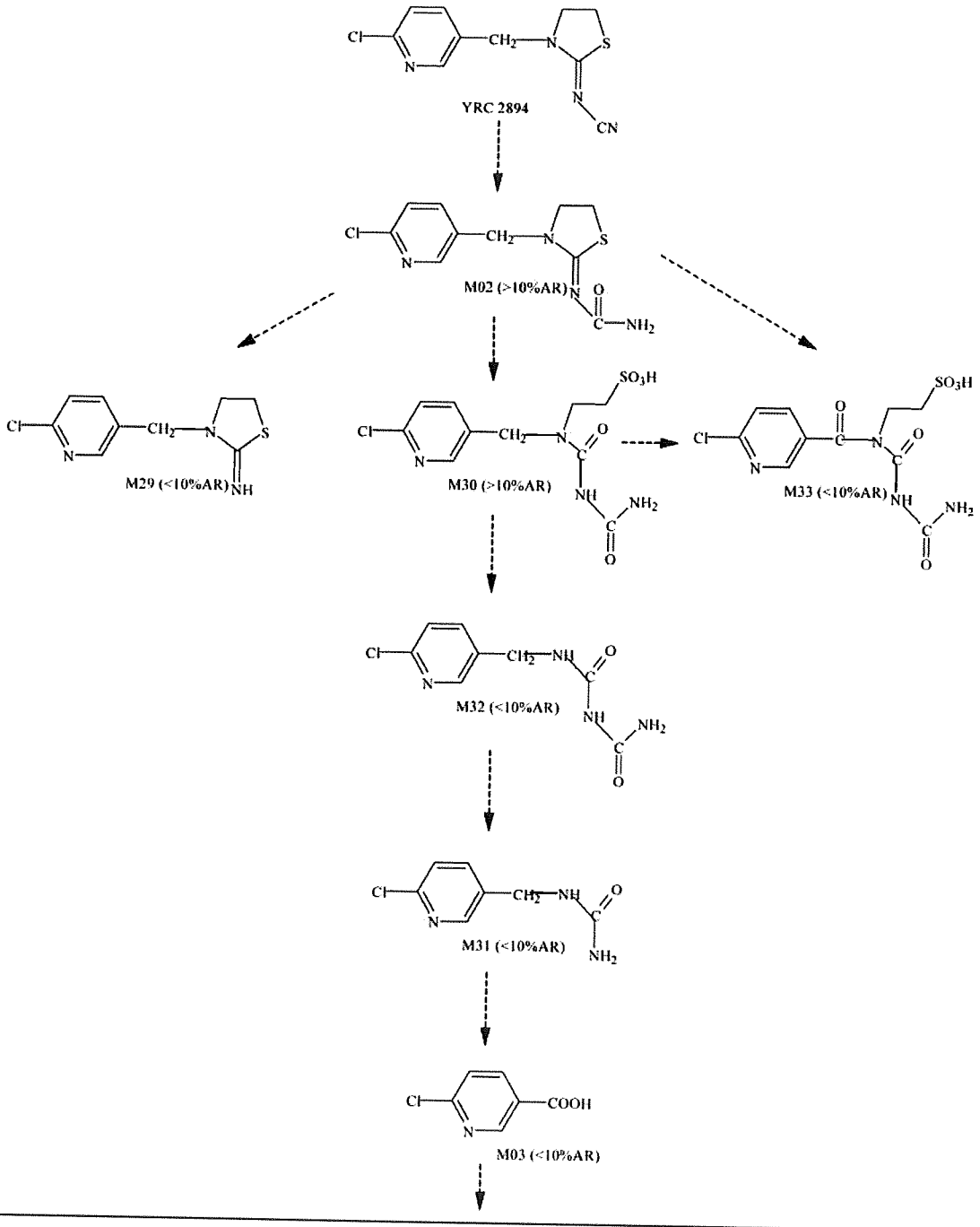
	BBA 2.1	BBA 2.2	Höfchen	Howe
Components at 100 d (% AR)				
YRC 2894 (thiacloprid)				
M02				
M30				
CO_2				
Non-extractable				
Maximum for M02 (%AR)				
Peak date for M02 (DAT)				
Maximum for M30 (%AR)				
Peak date for M30 (DAT)				

Table A7_2_1-2 **DT_{50} and DT_{90} values (in days) for YRC 2894 (thiacloprid) for the four soils calculated using different methods**

	Best fit with curve fitting				First-order kinetics with curve fitting*		First-order kinetics with linear regression			Graphical method	
	DT_{50}	DT_{90}	Best fit	r^2	DT_{50}	DT_{90}	DT_{50}	DT_{90}	r^2	DT_{50}	DT_{90}
BBA 2.1											
BBA 2.2											
Höfchen											
Howe											

* no r^2 provided by the applicant

Figure A7_2_1-1 **Proposed degradation pathway of thiacloprid in soil**



Section A7.2.2.1

Annex Point: IIIA XII 1.1

The rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions (1)

M02

			Official use only
		1 REFERENCE	
1.1	**Reference**	Schäfer, H. (1998 *[Monograph: 1998a]*): Calculation of DT-50 values of YRC 2894 metabolite KKO 2254 in soil under aerobic conditions Bayer AG, Report No. MR-241/98, date: 1998-03-02. *PPP-Monograph Chapter: B.8.1 Route and rate of degradation in soil B.8.1.1 Aerobic and anaerobic studies.B.1.1.1 Soil microbial studies. B.1.1.1.2 Soil rate of degradation studies-laboratory (Study 1)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Calculations for metabolite M02 were based on data obtained with the soil degradation method of the German BBA (Part IV, 4-1) and US-EPA (Pesticide Assessment Guidelines Subdivision N, Series 162-1), *cf.* study summary from section A7.2.1	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		The calculation of the disappearance times (DT_{50} and DT_{90}) of the main soil metabolite of YRC 2894 (thiacloprid), i.e. the amide metabolite (KKO 2254, M02) was conducted in those four soils which have also been used in the aerobic metabolism and degradation study on the parent compound (Fritz and Bornatsch, 1998; see A7.2.1).	X
		4 RESULTS	
		The degradation behaviour of the amide metabolite M02 was quantified using data from aerobic laboratory degradation studies with the parent compound (Fritz and Bornatsch, 1998) for four soils. First-order kinetics were applied to the two individual steps of the degradation pathway (transformation of YRC 2894 to M02, degradation of M02) with the simplifying assumption that degradation of YRC 2894 followed first-order kinetics. DT_{50} and DT_{90} values were obtained by non-linear fitting using the software ACSL Optimize (Table A7_2_2_1-1).	

Section A7.2.2.1

Annex Point: IIIA XII 1.1

The rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions (1)

M02

5 CONCLUSION

5.1 Conclusion

M02 (thiacloprid metabolite in soil) was estimated to have a DT_{50} of 32-142 days depending on the soil conditions. This indicates this metabolite is more stable in soil than its parent substance. X

[redacted]

5.1.1 Reliability [redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	27/07/2006
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_2_2_1-1 DT_{50} and DT_{90} values for M02 for four soils calculated by assuming first-order kinetics for each of the two steps of a simplified degradation pathway

	DT_{50} (days)	DT_{90} (days)
soil BBA 2.1	[redacted]	[redacted]
soil BBA 2.2	[redacted]	[redacted]
soil Höfchen	[redacted]	[redacted]
soil Howe	[redacted]	[redacted]

Section A7.2.2.1

Annex Point: IIIA XII 1.1

The rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions (2)

M30

			Official use only
		1 REFERENCE	
1.1	**Reference**	Hellpointner, E. (1998a): Degradation of [methylene-^{14}C]WAK 6999 in three soils. Bayer AG, Report No. PF4334, date: 1998-02-11. *PPP-Monograph Chapter: B.8.1 Route and rate of degradation in soil B.8.1.1 Aerobic and anaerobic studies.B.1.1.1 Soil microbial studies. B.1.1.1.2 Soil rate of degradation studies-laboratory (Study 3)* Additional calculations: Schad, T. (2002): Calculation of DT50 values of the YRC 2894 metabolite YRC 2894-sulfonic acid amid (M34) based on aerobic soil degradation studies. Bayer AG, Report No. MR-084/02, date: 2002-02-28. *Addendum 1 to PPP-Monograph: Chapter: B.8.1 Route and rate of degradation in soil B.8.1.1 Aerobic and anaerobic studies*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; German BBA (Part IV, 4-1) and SETAC guidelines.	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	

Section A7.2.2.1

Annex Point: IIIA XII 1.1

The rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions (2)

M30

Hellpointner, 1998a:

[14C]M30 was added in methanol and water at a concentration of 0.194 mg a.s./kg dry soil (equivalent to 0.140 kg a.s./ha, soil depth 5 cm, bulk density 1.5 g/cm3, 40% conversion of YRC 2894, i.e. thiacloprid) to separate fresh samples (100 g dry weight equivalent) of three biologically-active pre-incubated soils (2 mm sieved after gentle air drying) originating from Howe, Indiana, US ('Howe', 0-15 cm, sandy loam, pH 6.7, 1.12% oc), Jockgrim, Südpfalz, Germany ('BBA 2.1', 0-30 cm, sand, pH 5.9, 0.7% oc) and Hanhofen, Vorderpfalz, Germany ('BBA 2.2', 0-30 cm, loamy sand, pH 6.0, 2.48% oc).

All incubation vessels (300 ml) were closed with trap attachments for CO2 and organic volatiles (soda lime and glass wool, respectively) and aerobically incubated at 20 ± 1°C in the dark for a maximum of 101 days with soil maintained at 45% WHC. After 0, 2 hours, 3 , 7, 14, 30, 56, 77 and 101 days of incubation, radioactivity from replicate soil samples was extracted with water and then water/methanol/1N HCl (800 + 200 + 2 parts by volume) before quantification by LSC and identification by TLC against authentic samples, MS and NMR. [14]CO2 radioactivity was measured by LSC (PU-foam plugs were not analysed because material balances were complete). Unextracted radioactivity was determined by LSC after combustion.

Schad, 2002:

The data from the above study were evaluated using the Modelmaker (V4.0) software according to the degradation pathway defined using first order kinetics between the compartments with the fit optimised using Marquardt least squares statistics.

4 RESULTS

Section A7.2.2.1

Annex Point: IIIA XII 1.1

The rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions (2)

M30

Total recovery of radioactivity during the incubation period of 101 days ranged from 96 to 102% for all soils. The extraction efficiency by water (first extraction) decreased sharply from 2 hours after application (71% for Howe, 76% for BBA 2.1, 63% for BBA 2.2) to day 101 (3% for Howe, 47% for BBA 2.1, 1% for BBA 2.2). Similar patterns were observed in the two other soils. Table A7_2_2_1-1 presents the distribution of radioactivity at the end of the study period and maximum accumulation of metabolites. Three metabolites were observed and two were identified as YRC sulfonic acid amide (M34) and YRC 2894 diamide (M32).

Degradation of M30 best fitted 1st order, 2nd order and 1st order for the soils Howe, BBA 2.1 and BBA 2.2, respectively. DT_{50} and DT_{90} values for M30 for the three soils calculated by linear regression (first-order kinetics) by the applicant are presented in Table A7_2_2_1-2. The much larger half-life in the soil BBA 2.1 was attributed to its lower microbial biomass before the addition of the test substance (134 mg C/kg soil) compared to the two other soils (Howe 275 mg C/kg soil, BBA 2.2 342 mg C/kg soil).

The first rate orders calculated by Schad (2002) with another method for M30 and metabolite M34 are outlined in Table A7_2_2_1-3 and -4.

5 CONCLUSION

5.1 Conclusion

M30 (metabolite detected in the initial soil biodegradation study) was tested for soil degradation and resulted to be well degradable in soil (DT_{50} of 16-79 days depending on the soil conditions). Three metabolites were observed and two were identified as YRC sulfonic acid amide (M34) and YRC 2894 diamide (M32). The M34-DT_{50} was calculated to be between 7.8 and 52.5 days.

X

[redacted]

5.1.1 Reliability

[redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	28/07/2006
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_2_2_1-1 **Distribution of radioactivity at day 101 and maximum concentrations of M30 in the four soils**

	Howe	BBA 2.1	BBA 2.2
Components at 100 d (% AR)			
M30			
M34			
M32			
Metabolite D (*unidentified*)			
CO_2			
Non-extractable			
Maximum for M34 (%AR)			
Peak date for M34 (DAT)			
Maximum for M32 (%AR)			
Peak date for M32 (DAT)			
Maximum for Metabolite D (%AR)			
Peak date for Metabolite D (DAT)			

Table A7_2_2_1-2 **DT_{50} and DT_{90} values for M30 for the three soils calculated by first-order kinetics using linear regression**

	DT_{50} (days)	DT_{90} (days)	r^2
soil BBA 2.1			
soil BBA 2.2			
soil Howe			

Table A7_2_2_1-3 **First order rate constant, DT_{50} and DT_{90} values for M30 for the three soils calculated by first-order kinetics of Modelmaker (V4.0) software**

	Rate constant (days)	DT_{50} (days)	DT_{90} (days)	r^2
soil BBA 2.1				
soil BBA 2.2				
soil Howe				

Table A7_2_2_1-4 **First order rate constant, DT_{50} and DT_{90} values for M34 for the three soils calculated by first-order kinetics of Modelmaker (V4.0) software**

	Rate constant (days)	DT_{50} (days)	DT_{90} (days)	r^2
soil BBA 2.1	[redacted]	[redacted]	[redacted]	[redacted]
soil BBA 2.2	[redacted]	[redacted]	[redacted]	[redacted]
soil Howe	[redacted]	[redacted]	[redacted]	[redacted]

Section A7.2.2.2 Field soil dissipation and accumulation (1)

Annex Point: IIIA XII 1.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	Sommer, H. (1997d): Dissipation of YRC 2894 (480 SC) in soil under field conditions (France, Germany, Great Britain). Bayer AG, Report Nos. RA-2076/95 (R502855, R502863, R502871, R505633, R505641, R505668), date: 1997-11-14. *PPP-Monograph Chapter: B.8.1 Route and rate of biodegradation in soil B.8.1.3 Field studies. B.8.1.3.1. Field dissipation studies (Study 1)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; Commission Directive 95/36/EC of 14 July 1995 amending Council Directive 91/414/EEC German BBA guideline IV-4.1 (1986)	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		Six field dissipation studies were conducted in northern Europe. It should be noted that three of the six sites were cropped after application.	X
		Non-radiolabelled YRC 2894 (thiacloprid) was sprayed in spring (11 April to 3 May 1995) or summer (French site only, 24 July 1995) on bare soil at six sites (Table A7_2_2_2-1) selected as typical of agricultural regions of France, Germany and the UK. Following the single application (equivalent rate of 288 g a.s./ha as 480 SC formulation) with a water rate of 200-300 l/ha, three sites were cropped with grass whilst the three others were kept bare by manual or mechanical weed control (application of 'Roundup' on 5 September 1996 for the Burscheid site). Neither site characteristics other than soil properties nor history of pesticide treatment were specified.	
		Soil samples were collected immediately after application and on 11 occasions thereafter (last sampling occasion occurred 713-723 days after treatment). On each occasion, 20 (all treated samples and control samples for the UK sites) or 10 (control samples for the other sites) cores (i.d. 5 cm) were randomly collected ("Wacker Hammer", i.d. 5 cm) from the study sites to a depth of 50 cm. Additional core samples were taken at day 0 using a "Piercer" to a depth of 10 cm. Samples	

were frozen, segmented into 10-cm portions, milled, homogenised and kept below -18°C prior to analysis. Samples were extracted (methanol / water/ 1N HCl, 800+200+2 parts by volume), concentrated and analysed for YRC 2894 and the two metabolites M02 and M30 by HPLC - MS/MS and reference compounds. Mean recoveries for the analytical method were 97.4% (standard deviation 4.9%) for YRC 2894, 90.0% (s.d. 9.3%) for M02 and 86.9% (s.d. 9.8%) for M30. The limits of detection and quantification were 2 and 5 µg/kg, respectively. Recovery experiments were conducted at a range of fortification levels (from 6.4 to 159 µg a.s./kg of soil).

Weather data for the six study sites are reported in Table A7_2_2_2-2. The Burscheid site was the wettest and the Wellesbourne site the driest. Long-term data to assess how representative the study periods were of the climate are not provided in the report except for Burscheid and Monheim. For these two sites, rainfall over the 24-month period was about 80% of the long-term average. The study periods for the two UK sites were "drier than usual". Rainfall (6 mm at <1 mm/h) was recorded in the afternoon of the day of application for the Monheim site.

4 RESULTS

Mean concurrent recoveries were 94% for YRC 2894, 86% for M02 and 84% for M30. Residues of YRC 2894 in samples collected immediately after application represented between 72% (L'Archevêque) and 102% (Burscheid, Monheim) of that expected from theoretical application rates (bulk density of 1.5 g/cm3, 10 cm depth). Similar patterns were observed for the five other sites. Maximum residues and residues at the end of the study period for the parent and its two metabolites for the top 10 cm at the six sites are presented in Table A7_2_2_2-3. Detailed evolution of YRC 2894 residues in the top 10 cm is presented in Table A7_2_2_2-4. All residues for YRC 2894 and M02 were below the limit of detection (<2 µg/kg dry soil) in the 10-20 cm layer. The sulfonic acid metabolite M30 was detected at <5 µg/kg in the 10-20 cm layer on three sampling occasions (60 days after treatment for L'Archevêque and the Monheim sites, 158 days after treatment for the Wellesbourne site). No residues >2 µg/kg dry soil were detected in the 20-30 cm layer throughout the study period.

Residues for YRC 2894 were used as input for the programme of Timme et al. to determine DT_{50} and DT_{90} values. Best fits were obtained with 1st and sqrt 1st orders. DT_{50} and DT_{90} values are presented in Table A7_2_2_2-5. Table A7_2_2_2-6 presents DT_{50} values for M02 and M30 as calculated from soil residues using first order-kinetics and linear regression (those sites where three or more data points were available from the peak metabolite concentration).

Section A7.2.2.2 Field soil dissipation and accumulation (1)

Annex Point: IIIA XII 1.1

5 CONCLUSION

5.1 Conclusion

In summary, the results of the six trials are showing that the translocation of traces of YRC 2894, M02 or M30 into deeper soil layers of 20-30 cm can be excluded down to a concentration of 2 µg/kg corresponding to less than 1 % of the initial concentration of the active substance.

DT_{50} demonstrates that YRC 2894 is well degradable in soil under field conditions (3-27 days). M02 and M30 had longer half-lives.

[redacted]

X

5.1.1 Reliability

[redacted]

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 13/09/2006

Materials and Methods

[redacted]

Results and discussion

[redacted]

Conclusion

[redacted]

Reliability

[redacted]

Acceptability

[redacted]

Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_2_2_2-1 Characteristics of the six study sites

Location	Country	Plot size m^2	Texture (0-30cm)	% oc	pH $CaCl_2$	Post-application cropping
Swisttal-Hohn	Germany	255	sandy silt loam	0.85	6.7	bare
Bury St. Edmunds	UK	390	sandy loam	0.88	6.9	bare
L'Archevêque	France	360	loamy sand	1.01	7.5	grass
Burscheid	Germany	225	silty clay loam	0.91	6.7	bare
Monheim	Germany	255	sandy loam	1.12	6.7	grass (ryegrass)
Wellesbourne	UK	390	sandy loam	1.26	6.0	grass

Table A7_2_2_2-2 **Summary of monthly rainfall (Rain, mm) and average air temperature (Tem, °C) for the six sites over the study period**

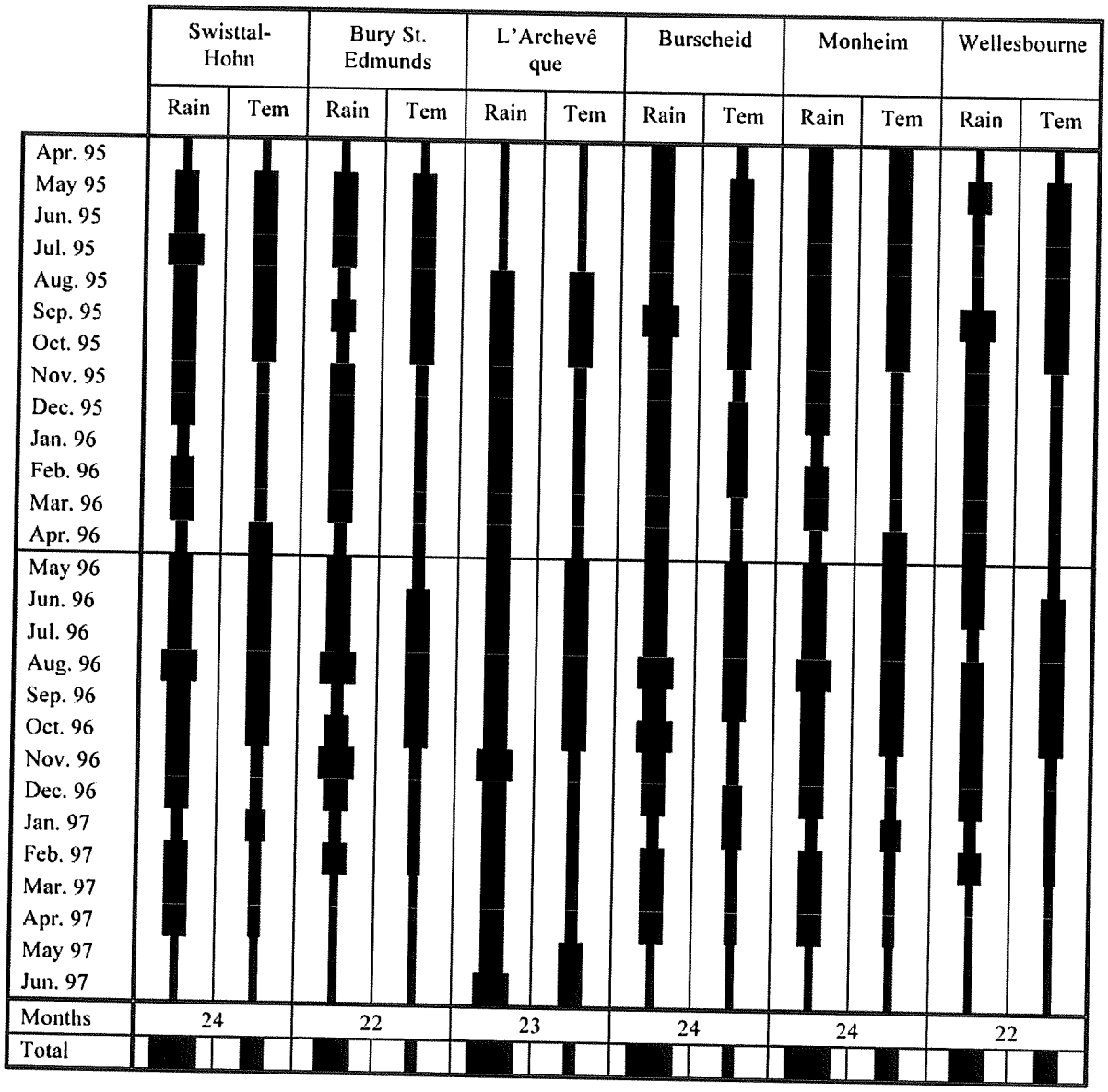


Table A7_2_2_2-3 **Maximum residues and residues at the end of the study period for YRC 2894 (thiacloprid), M02 and M30 at the six sites (top 10 cm only)**

	Swisttal-Hohn	Bury St Edmunds	L'Archevê-que	Burscheid	Monheim	Wellesbourne
YRC 2894						
Max (µg/kg)						
Peak (DAT)						
Conc. at end (µg/kg)						
M02						
Max (µg/kg)						
Peak (DAT)						
Conc. at end (µg/kg)						
M30						
Max (µg/kg)						
Peak (DAT)						
Conc. at end (µg/kg)						

Table A7_2_2_2-4 **Residues of YRC 2894 (thiacloprid) in the top 10 cm of the six field dissipation studies. All concentrations expressed in mg a.s./kg dry soil**

DAT*	Swisttal-Hohn	Bury St Edmunds	L'Archevê-que	Burscheid	Monheim	Wellesbourne
0						
7						
15						
30						
60						
100						
150						
240						

DAT (day after treatment) is only an indication of the sampling date as actual dates differed slightly between studies

Table A7_2_2_2-5 **DT_{50} and DT_{90} values for dissipation of YRC 2894 (thiacloprid) in the top 10 cm of the six study sites (data up to 100 days only)**

	DT_{50} (days)	DT_{90} (days)	Best fit	r^2
Swisttal-Hohn				
Bury St Edmunds				
L'Archevêque				
Burscheid				
Monheim				
Wellesbourne				

* Values recalculated by using first-order kinetics (r^2=0.98) for L'Archevêque: DT_{50} 18 days, DT_{90} 59 days.

Table A7_2_2_2-6 **DT_{50} values for dissipation of M02 and M30 in the top 10 cm of the six study sites using first-order kinetics and linear regression. The calculations were restricted to sites where more than two data points were available after the peak concentrations**

	M02 metabolite			M30 metabolite		
	DT_{50} (days)	r^2	No. of points	DT_{50} (days)	r^2	No. of points
Swisttal-Hohn						
Bury St Edmunds						
L'Archevêque						
Burscheid						
Monheim						
Wellesbourne						

Section A7.2.2.2 Field soil dissipation and accumulation (2)

Annex Point: IIIA XII 1.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	Sommer, H. (1998b *[Monograph: 1998a]*): Dissipation of YRC 2894 (480 SC) in soil under field conditions (France and Spain). Bayer AG, Report Nos. RA-2077/95 (R502898, R502928), date: 1998-01-22. *PPP-Monograph Chapter: B.8.1 Route and rate of biodegradation in soil B.8.1.3 Field studies. B.8.1.3.1. Field dissipation studies (Study 2)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; Commission Directive 95/36/EC of 14 July 1995 amending Council Directive 91/414/EEC German BBA Guideline IV-4.1 (1986)	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		The two study sites were 300 m^2 bare soil plots in Laudun, southern France (clay loam, pH CaCl2 7.8, 1.06% oc) and Torrebonica, Spain (clay loam, pH CaCl2 7.7, 0.97% oc). YRC 2894 (thiacloprid) was sprayed in spring 1995 at the two study sites (288 g a.s./ha, 480 SC formulation, 280-300 l/ha). Soil cores were taken directly following application and at ten or eleven intervals thereafter. Glyphosate ('Herbolex', 6 litres/ha) was applied at the Torrebonica site in August 1996. All other experimental and analytical procedures were similar to those described in A7.2.2.2, Study 1 (HPLC - MS/MS).	X
		Weather data for the six study sites are reported in Table A7_2_2_2-1. Comparisons with long-term averages were not made.	
		4 RESULTS	
		Mean concurrent recoveries were 91% for YRC 2894, 92% for M02 and 78% for M30.	X
		Residues of YRC 2894 in the top 10 cm of the six field trials are reported in Table A7_2_2_2-2. Post-application residues were 104% and 87% of the applied amount on day 0 for Laudun and Torrebonica, respectively. Residues of parent compound in the top 0-10 cm decreased such that they were below the limit of detection after 62 days	

Section A7.2.2.2 Field soil dissipation and accumulation (2)

Annex Point: IIIA XII 1.1

(Laudun) or after 154 days (Torrebonica). Maximum accumulation of M02 occurred on day 7 in Laudun (0.091 mg/kg) and on day 28 in Torrebonica (0.058 mg/kg). Maximum accumulation of M30 was 0.013 mg/kg on day 100 at Laudun and 0.006 mg/kg on day 60 at Torrebonica. For the Torrebonica site, isolated detections of YRC 2894 (0.0135 mg a.s./kg on day 0 and <0.005 mg a.s./kg on day 6) and M02 (<0.005 mg/kg on day 6) were reported in the 10-20 cm layer. Also, YRC 2894 was detected at day 0 (<0.005 mg a.s./kg) in the 20-30 cm layer. Neither YRC 2894 nor its two main metabolites were detected in the 10-20 or 20-30 layers from the Laudun site.

Residues for YRC 2894 were used as input for the programme of Timme et al. to determine DT_{50} and DT_{90} values. Best fits were obtained with first-order kinetics (Table A7_2_2_2-3). Soil residues for the two major metabolites M02 and M30 were used to calculate DT_{50} and DT_{90} values using first-order kinetics (Table A7_2_2_2-3).

5 CONCLUSION

5.1 Conclusion

In summary, the results of the two trials are showing that except for one sample at day 0 the translocation of traces of YRC 2894, M02 or M30 into deeper soil layers of 20-30 cm can be excluded down to a concentration of 2 µg/kg corresponding to less than 1 % of the initial concentration of the active substance.

DT_{50} demonstrates that YRC 2894 is well degradable in soil under field conditions (10-16 days). M02 and M30 had longer half-lives.

[redacted]

X

5.1.1 Reliability

[redacted]

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 06/09/2006

Materials and Methods

[redacted]

Results and discussion

[redacted]

Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_2_2_2-1 **Summary of monthly rainfall (mm) and average air temperature (°C) for the two sites over the study period**

	Laudun (France)		Torrebonica (Spain)	
	Rain	Air temp.	Rain	Air temp.
May 95	45	16	25	14
Jun. 95	9	20	7	18
Jul. 95	31	25	3	23
Aug. 95	34	24	43	22
Sep. 95	137	17	118	17
Oct. 95	102	17	29	17
Nov. 95	127	10	70	11
Dec. 95	90	6	63	9
Jan. 96	181	8	116	9
Feb. 96	60	5	13	7
Mar. 96	73	9	0	9
Apr. 96	43	13	79	13
May 96	>37*	17	66	14
Jun. 96	57	21	100	20
Jul. 96	70	23	16	22
Aug. 96	111	22	78	22
Sep. 96	53	17	70	18
Oct. 96	55	14	29	15
Nov. 96	242	9	131	12
Dec. 96	103	6	101	7
Jan. 97	155	5	90	7
Feb. 97	3	8	0	10
Mar. 97	2	14	6	12
Apr. 97	17	13	-	-
Months	24	24	23	23
Total	>1837	14	1253	14

* No weather data for the first 10 days of May 96

Table A7_2_2_2-2 **Residues of YRC 2894 (thiacloprid) in the top 10 cm of the six field dissipation studies. All concentrations expressed in mg a.s./kg dry soil**

Date	Laudun (France)	Date	Torrebonica (Spain)
0		0	
7		6	
14		14	
30		28	
62		60	
100		103	
152		154	

Table A7_2_2_2-3 **DT_{50} and DT_{90} values for dissipation of YRC 2894 (thiacloprid) and the two metabolites M02 and M30 in the top 10 cm of the two study sites**

	YRC 2894			Metabolite M02			Metabolite M30		
	DT_{50}	DT_{90}	r^2	DT_{50}	DT_{90}	r^2	DT_{50}	DT_{90}	r^2
Laudun (F)									
Torrebonica (SP)									

Section 7.2.2.3 Annex Point IIIA 12.1.4	Extend and nature of bound residues	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] Limited exposure [...]	Technically not feasible [ ] Scientifically unjustified [ ] Other justification [...]	
Detailed justification:	Information on bound residues are given in the laboratory studies on degradation in soil and e.g. summarised in the study summaries IIIA7.2.1 aerobic degradation (in soil) (1) and (2). The bound residues are there quantified and in addition characterised by extraction methods and assignment to humic acid fractions. Non-submission on studies on extend and nature of bound residues is therefore justified.	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	10/08/2006	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	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 A7.2.2.4 Other soil degradation studies

Annex Point: IIIA XII 1.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	Hellpointner, E. (1998b): Photolysis of [^{14}C]YRC 2894 on soil surface. Bayer AG, Report No. PF4333, date: 1998-02-26. *PPP-Monograph Chapter: B.8.1 Route and rate of degradation in soil. B.8.1.2 Photolysis on soil*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; US-EPA (Pesticide Assessment Guidelines Subdivision N, Series 161-3) and SETAC guidelines on photolysis	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		Samples of US 'Howe' sandy loam soil (2 mm sieved; air-dried; pH 7.1, 1.1% oc) were taken from wooden stores under field-like conditions and placed in round glass vessels (base area 10.2 cm2, height 3.5 cm) to give a 2-mm soil layer. [14C]YRC 2894 (thiacloprid) dissolved in ethanol was diluted approximately 1:18 with water and added to test vessels at 2.33 mg a.s./kg and resulting in a moisture content of 75% of that at 0.33 bar. All treated vessels were sealed and maintained at 25 ± 1°C with traps for CO_2 and organic volatiles (soda lime and PU foam, respectively). Irradiated samples were kept in a Suntest cabinet exposed to a xenon lamp (NXe 1500B; continuous irradiation at an average of 9.3×10-3 W/cm2; >290 nm) for up to 18 days. Dark control samples were maintained in an incubator for up to 19 days.	X
		Duplicate soil samples were taken for analysis at 0, 7 and 19 days after application (dark control) and 0, 4, 7, 13 and 18 days after application (irradiated). The last irradiated sample was exposed to light for an additional period to compensate for light failure (11 h) 15 days after application. Radioactivity from soil samples was extracted with methanol at room temperature and additionally with water/methanol (1:1 v/v) using Soxtec apparatus at 180°C. Radioactivity was quantified by LSC and analysed by TLC and HPLC. Metabolites were identified through comparison with reference substances. Unextracted radioactivity was quantified by combustion analysis. Radioactivity in trapping solutions was quantified by LSC.	

Section A7.2.2.4 Other soil degradation studies

Annex Point: IIIA XII 1.1

4 RESULTS

Recovery from all samples was 99-102% AR. Extractable radioactivity declined to 90 and 92% AR after 18/19 days for irradiated and control samples, respectively. Volatile components did not exceed 0.3% AR. After 18/19 days, YRC 2894 accounted for a mean of 47.5 and 11.1% AR in irradiated and dark control samples, respectively. The only major metabolite was identified as M02 and accounted for 23.8 and 69.6% AR after 19 days in irradiated and control samples, respectively.

DT_{50} values were determined by linear regression using first-order kinetics (r^2 = 0.98-0.99). The mean DT_{50} for degradation of YRC 2894 was 18.8 days continuous irradiation (equivalent to 74 solar summer days for Phoenix, Arizona, USA) for illuminated samples and 6.3 days for dark controls.

5 CONCLUSION

5.1 Conclusion

The mean DT_{50} of YRC 2894 in soil was estimated to be 18.8 days under continuous irradiation (equivalent to 74 solar summer days for Phoenix, Arizona, USA) for illuminated samples and 6.3 days for dark controls. No explanation was provided for the faster degradation in the dark controls relative to the irradiated samples. X

[redacted]

5.1.1 Reliability [redacted] X

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	18/12/2006
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

COMMENTS FROM ...

Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.2.3.1

Annex Point IIIA XII 1.2

Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products (1)

			Official use only
		1 REFERENCE	
1.1	**Reference**	Henneböle, J. (1994): Adsorption/desorption of YRC 2894 on soils. Bayer AG, Report No. PF3980, date: 1994-06-09, *revised 1995-12-05.* Henneböle, J. (1999): Adsorption/desorption of YRC 2894 on soils. Bayer AG, Report No. PF3980 (also MS 930), date: *revised 1999-10-20.* *PPP-Monograph Chapter: B.8.2. Adsorption, desorption and mobility in soil. B.8.2.1 Batch adsorption and desorption (Study 1)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; US-EPA guidelines (Pesticide Assessment Guidelines, Subdivision N, Series 163-1)	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		For the study with the parent compound, [14C]YRC 2894 (thiacloprid) in 0.01M aqueous CaCl2 (20 ml) was added to samples (6 g dry weight; 2 mm sieved after air-drying) of six soils (0-30 cm for Borstel, 0-15 cm for the American soils except Napa 5-15 cm; Borstel soil freshly collected from the field and kept at 4°C, American soils freshly collected from wooden boxes under field conditions), at concentrations of 0.013, 0.065, 0.099 and 0.130 mg a.s./litre for each soil. Further information on the soils is presented in Table A7_2_3_1. After addition of mercury chloride (50 mg HgCl2/l), treated slurries were shaken (25 rpm) for 24 hours in the dark at 20 ± 1°C (equilibrium confirmed in pre-test). After equilibration, the supernatant from duplicate samples was removed by centrifugation and radioactivity quantified by LSC and identified by TLC. Adsorbed YRC 2894 was calculated by difference. Following the adsorption stage (for samples with largest concentration only), soil pellets were resuspended in 0.01M CaCl2 (20 ml), shaken for 24 hours and centrifuged (15 min, 6000 g). Supernatants were analysed as above. This desorption stage was performed four successive times for each soil.	X

Section A7.2.3.1
Annex Point IIIA XII 1.2

Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products (1)

4 RESULTS

Total recoveries for adsorption were 94-102% AR. Adsorption and desorption isotherms were used to calculate Freundlich coefficients (Kf) and Koc values for each soil, which are given in Table A7_2_3_1-1.

Desorption resulted in the release of 15-67% of the YRC 2894 that was initially adsorbed. Samples for 0.130 mg a.s./litre not treated with mercury chloride resulted in 85-94% of the measured radioactivity attributed to YRC 2894, compared to >98% for samples treated with mercury chloride (no further information provided).

5 CONCLUSION

5.1 Conclusion

With a Koc of 393-870 thiacloprid can be classified as a substance with middle potential for mobility in soil according to the criteria of McCall (1980). X

[redacted]

5.1.1 Reliability [redacted]

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	24/07/2006
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

COMMENTS FROM ...

Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_2_3_1-1 **Adsorption and desorption coefficients for YRC 2894 (thiacloprid) for six soils. The texture is given according to the USDA classification. Kf and Koc are given in ml/g**

Soil	Texture	% oc	pH	Adsorption			Desorption		
				1/n	K_f	K_{oc}	1/n	K_f	K_{oc}
Borstel, Germany	sandy loam	1.15	6.3	[redacted]					
Howe, Indiana, US	sandy loam	0.75	7.1	[redacted]					
Stanley, Kansas, US	silty clay	1.05*	5.6	[redacted]					
Vero Beach, Florida, US	sand	0.2	5.1	[redacted]					
Grape Vineyard, California, US	sandy loam	0.45	6.7	[redacted]					
Napa, California, US	loam	0.99	7.7	[redacted]					

* [redacted] in the original study report. Koc values reported here are changed according to the corrected % oc value.

Section A7.2.3.1

Annex Point IIIA XII 1.2

Adsorption and desorptionin accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products (2)

M02

			Official use only
		1 REFERENCE	
1.1	**Reference**	Graney, R. (1995): Adsorption/desorption of KKO 2254 on soils. Bayer AG, Report No. PF4062, date: 1995-06-26. *PPP-Monograph Chapter: B.8.2. Adsorption, desorption and mobility in soil. B.8.2.1 Batch adsorption and desorption (Study 2)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; US-EPA guidelines (Pesticide Assessment Guidelines, Subdivision N, Series 163-1)	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		A further batch adsorption/desorption study was conducted for the amide metabolite [14C-methylene]M02 on five of the six soils described in the study before of Hennböle (1994, 1999) for the determination of adsorption of thiacloprid (the Napa soil was excluded). Deviations from the protocol described in Hennböle (1994, 1999) included: i) 10 g of soil were used for the Vero Beach soil (least adsorptive soil); ii) concentrations of M02 were 0.02, 0.05, 0.10 and 0.20 mg M02/litre CaCl2 solution; iii) no mercury chloride was added to the soil/water slurries; iv) centrifugation was performed for 15 min at 10,000 g; and, v) desorption was limited to one step.	X
		4 RESULTS	
		Total recoveries for adsorption were 93-106% AR and 97% of the radioactivity could be assigned to M02. Freundlich parameters (Kf and 1/n) and Koc values for each soil are given in Table A7_2_3_1-1. On the basis of these findings (Koc 166-438 ml/g. The single desorption step resulted in the release of 23-63% of the M02 which was initially adsorbed. A large variability was noted for one replicate for the radioactivity balance (Stanley soil, initial concentration 0.02 mg M02/litre) and was attributed to instrumental difficulties. The	

Section A7.2.3.1
Annex Point IIIA XII 1.2

Adsorption and desorptionin accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products (2)

M02

		value was nevertheless kept as it did not significantly affect the estimation of sorption coefficients.	
		5 CONCLUSION	
5.1	**Conclusion**	With a Koc of 166-438 the metabolite M02 can be classified as a substance with middle potential for mobility in soil according to the criteria of McCall (1980).	X
		[redacted]	
5.1.1	Reliability	[redacted]	

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	24/07/2006
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

COMMENTS FROM ...

Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_2_3_1-1 **Adsorption and desorption coefficients for M02 for five soils. The texture is given according to the USDA classification**

Soil	Texture	% oc	pH	Adsorption			Desorption		
				1/n	K_f	K_{oc}	1/n	K_f	K_{oc}
Borstel	loamy sand	0.69	5.9	[redacted]					
Howe	sandy loam	1.12	6.7	[redacted]					
Stanley	silty clay	1.2	5.6	[redacted]					
Vero Beach	sand	0.2	5.1	[redacted]					
Grape Vineyard	sandy loam	0.45	6.7	[redacted]					

Section A7.2.3.1

Annex Point IIIA XII 1.2

Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products (3)

Metabolite M30

			Official use only
		1 REFERENCE	
1.1	**Reference**	Brumhard, B. (1998b): Adsorption/desorption of WAK 6999 on different soils. Bayer AG, Report No. PF4339, date: 1998-03-11. *PPP-Monograph Chapter: B.8.2. Adsorption, desorption and mobility in soil. B.8.2.1 Batch adsorption and desorption (Study 3)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; US-EPA guidelines (Pesticide Assessment Guidelines, Subdivision N, Series 163-1)	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	

3 MATERIALS AND METHODS

A third batch adsorption/desorption study was carried out for the sulfonic acid metabolite [14C-methylene]M30 using the same five soils as described in the study before of Graney (1995) to determine the adsorption of M02. Deviations from the protocol described in Graney (1995) included: i) 20 g of soil were used for the Howe and Stanley soils and 25 g of soil were used for the Borstel, Vero Beach and Grape Vineyard soils; ii) concentrations of M30 were 0.005, 0.05, 0.5 and 5 mg M30/litre $CaCl_2$ solution; iii) centrifugation was performed for 15 min at >3400 g; and, iv) identification of possible metabolites was conducted by TLC and HPLC.

4 RESULTS

Total recoveries for adsorption were 93-103% AR and the radioactivity was assigned completely to M30. Freundlich coefficients (Kf) and Koc values for each soil are given in Table A7_2_3_1-1.

The single desorption step resulted in the release of 25-53% of the M30 which was initially adsorbed.

Section A7.2.3.1

Annex Point IIIA XII 1.2

Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products (3)

Metabolite M30

5 CONCLUSION

5.1 Conclusion

With a Koc of 11.9-28.2 the metabolite M30 can be classified as a substance with low potential for mobility in soil according to the criteria of McCall (1980).

X

[redacted]

5.1.1 Reliability

[redacted]

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	25/07/2006
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

COMMENTS FROM ...

Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_2_3_1-1 **Adsorption and desorption coefficients for M30 for five soils. The texture is given according to the USDA classification**

Soil	Texture	% oc	pH	Adsorption			Desorption		
				1/n	K_f	K_{oc}	1/n	K_f	K_{oc}
Borstel	loamy sand	0.69	5.9	[redacted]					
Howe	sandy loam	1.12	6.7	[redacted]					
Stanley	silty clay loam	1.49	6.1	[redacted]					
Vero Beach	sand	0.32	7.0	[redacted]					
Grape Vineyard	sandy loam	0.45	6.7	[redacted]					

Section A7.2.3.1

Annex Point IIIA XII 1.2

Adsorption and desorption accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products (4)

Metabolite M34

			Official use only
		1 REFERENCE	
1.1	**Reference**	Stupp, H. P. (2002a): Adsorption and desorption of YRC2894-sulfonic acid amide in soils. Bayer AG, Report No. MR-102/02, date: 2002-03-08. *Addendum I to PPP-Monograph; Chapter: B.8.2. Adsorption, desorption and mobility in soil. B.8.2.1 Adsorption and desorption*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; US-EPA (Pesticide Assessment Guidelines Subdivision N, Series 163-1, 1982) and OECD guideline 106 (2000).	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		A batch equilibrium adsorption/desorption study was conducted for thiacloprid-sulfonic acid amide (M34).	X
		[14C-methylene]-M34 in 0.01 m calcium chloride (20 ml) was added to duplicate samples (10 or 20 g) of four soils (loamy sand, 2 sandy loams and a silty clay), at a concentration of 1 mg M34/litre for each soil. Treated slurries were shaken in 'Teflon' tubes at 20°C for 72 hours in the dark. After this period, the supernatant was removed by centrifugation and radioactivity quantified by LSC and analysed by HPLC. Adsorbed M34 was calculated by difference.	
		4 RESULTS	
		A soil adsorption partition coefficient (Kd) and Koc values for each soil, which are given in Table A7_2_3_1-1 were calculated. No attempt was made to measure Freundlich adsorption coefficients because of the low adsorption of this compound.	

Section A7.2.3.1
Annex Point IIIA XII 1.2

Adsorption and desorption accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products (4)

Metabolite M34

5 CONCLUSION

5.1 Conclusion

The adsorption of metabolite M34 was examined beacause this was detected in the leachate of the lysimeter study on thiacloprid. At the same time, M34 was found to be the degradation product of M30 in a soil degradation test to determine the degradation route of the metabolite M30.

Based on the reported Koc values< 6.97, M34 can be classified as a substance with very low potential for mobility according to the criteria of McCall (1980).

X

[redacted]

5.1.1 Reliability

[redacted]

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 25/07/2006

Materials and Methods [redacted]

Results and discussion [redacted]

Conclusion [redacted]

Reliability [redacted]

Acceptability [redacted]

Remarks [redacted]

COMMENTS FROM ...

Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_2_3_1-1 **Adsorption coefficients for thiacloprid-sulfonic acid amide (M34) to four soils**

Soil type	% oc	pH	K_d	K_{oc}
BBA 2.2 loamy sand	[redacted]	6.2	[redacted]	[redacted]
Laacher Hof AXXa sandy loam	[redacted]	7.2	[redacted]	[redacted]
Boden LUFA-Apeyer sandy loam	[redacted]	6.6	[redacted]	[redacted]
Stanley silty clay	[redacted]	6.3	[redacted]	[redacted]

Section A7.2.3.2
Annex Point IIIA XII 1.3

Mobility in at least three soil types and where relevant mobility of metabolites and degradation products (1)

			Official use only
		1 REFERENCE	
1.1	**Reference**	Henneböle, J. (1995): Leaching behaviour of the crop protection compound YRC 2894 with previous ageing in soil. Bayer AG, Report No. PF4099, date: 1995-10-31, *revised 22.12.1995.* *PPP-Monograph Chapter: B.8.2 Adsorption, desorption and mobility in soil. B.8.2.2 Column leaching and lysimeter studies (Study 1)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; German BBA guidelines (Part IV, 4-2) "Aged column leaching study"	
2.2	**GLP**	[redacted]	X
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		[14C]YRC 2894 (thiacloprid) was added in acetonitrile to an air-dried pulverised subsample of Speyer 2.1 ('BBA 2.1', sand, pH in $CaCl_2$ 5.3, 0.7% oc) soil freshly sampled and stored under vegetation. After evaporation of the solvent, the aliquot was thoroughly mixed with the rest of the soil (<2 mm) to give a resulting concentration of 0.245 mg a.s./kg soil (dry weight). This was equivalent to a field application rate of 0.125 kg a.s./ha. Closed vessels containing the treated soil were fitted with a trap attachment for CO2 and volatile organic compounds (soda lime and polyurethane plug, respectively) and aerobically incubated at 20 ± 1°C in the dark for 30 or 60 days with the biologically active soil maintained at 40% WHC. The ageing time of 30 days differed from the initial study protocol, which proposed an ageing time of one half-life. Given the short half-life of YRC 2894 (<6 days as determined in screening tests), it was considered that the leaching behaviour of the rapidly formed, but slowly degradable, metabolites of YRC 2894 could be better assessed with a longer incubation period.	X
		Following incubation, radioactivity from replicated soil samples was extracted with methanol and water before quantification by LSC and identification by TLC and HPLC. Unextracted radioactivity was quantified by combustion analysis. Mean total recovery was 94-100% AR. YRC 2894 accounted for 1.1 %AR and 1.6% AR after ageing for 30 and 60 days, respectively. The two main metabolites were M02 (36% AR after 30 days, 25% after 60 days) and M30 (11% AR	

after 30 days, 15% AR after 60 days).Unknown metabolites (≥3) were detected at a maximum of 7% AR for the 60-day ageing samples. Approximately 5 and 8% AR was determined as CO2 for day 30 and day 60, respectively, whilst the unextractable radioactivity was 40% on day 30 and 43% on day 60.

Replicate 30 cm glass columns (i.d. 5 cm) were packed with the same untreated air dry, sieved (<1 mm) soil to a depth of approximately 28 cm. Samples (100g) of the respective treated soil, either immediately after treatment, after 30 days or 60 days of incubation as above, were then added to the top of duplicate columns previously saturated with distilled water. All columns were irrigated with water (393 ml) over 2 days (mean equivalent rainfall 4.2 mm/hour) and the leachate collected in four equal fractions of ca. 100 ml each. Radioactivity in the leachate was quantified by LSC and for radioactivity contents ≥0.4% AR, was identified by TLC/HPLC. Volatiles were not collected during leaching. Leached soil columns were frozen, divided into six equal segments and each segment was analysed for total radioactivity by LSC after air drying. Where radioactivity was >2% AR for the 30-day ageing column only, segments were extracted (methanol/water, 1:1) and radioactivity was identified by chromatography (method not specified).

4 RESULTS

Combined leachate from the soil columns contained totals of 14.5% AR (day 30) and 19.4% AR (day 60). YRC 2894 was not detected in leachate, M02 could only be detected for day-30 columns (0.1% AR) and M30 accounted for a total of 11.6% AR (day 30) or 18.5% AR (day 60). Unknown metabolites (≥3) accounted for 2% AR and 1% AR for day-30 and day-60 columns, respectively. The distribution of radioactivity in the segments of the day-30 column, which accounted for 89% AR (77% AR for the day-60 column), is presented in Table A7_2_3_2-1. Most of the radioactivity was confined to the top two segments and the extractable radioactivity from the column was mainly attributed to the amide metabolite M02.

5 CONCLUSION

5.1 Conclusion

Leachate and soil obtained after irrigation of the incubated soil at day 30 and 60 contained mainly the metabolites M30 and M02 respectively. Thiacloprid was not more detected in both leachate and soil at day 30 (except in the top soil layers). X

[redacted]

5.1.1 Reliability [redacted] X

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 02/08/2006

Materials and Methods [redacted]

Results and discussion [redacted]

Conclusion [redacted]

Reliability [redacted]

Acceptability [redacted]

Remarks [redacted]

COMMENTS FROM DE CA

Date *11.10.2007*

Materials and Methods [redacted]

Results and discussion

Conclusion

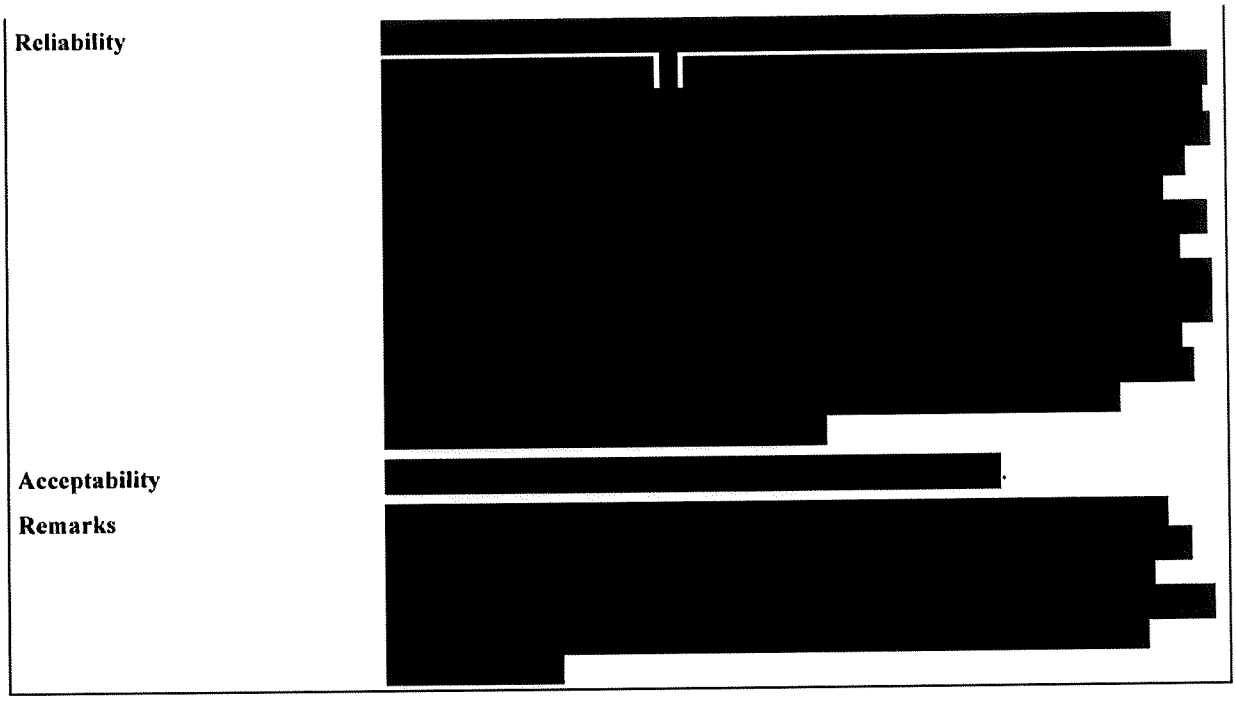


Table A7_2_3_2-1 **Distribution of radioactivity, YRC 2894 (thiacloprid) and metabolites in soil segments for the 30-day column (% AR, means of replicates unless specified presence of n.d.) Segment 1 is the top segment. Totals may not equal the sums of each column because of number rounding**

	Soil	Extracted	YRC 2894	M02	M30	Other metabolites
Segment 1	59.6	17.0				
Segment 2	13.2	7.9				
Segment 3	9.0	5.8				
Segment 4	3.2	3.1 / n.d.				
Segment 5	2.2	3.0 / n.d.				
Segment 6	0.8	n.d.				
Total	88.7	33.6				

Section A7.2.3.2
Annex Point IIIA XII 1.3

Mobility in at least three soil types and where relevant mobility of metabolites and degradation products (2)

			Official use only
		1 REFERENCE	
1.1	**Reference**	Brumhard, B. (1998c): Lysimeter study for testing the leaching behaviour of YRC 2894 in case of repeated application on grass. Bayer AG, Report No. PF4342, date: 1998-07-02. *PPP-Monograph Chapter: B.8.2 Adsorption, desorption and mobility in soil. B.8.2.2 Column leaching and lysimeter studies (Study 2)* Recalculations of Z5 concentration: - Schaefer, H. (2002 *[Monograph: 2002b]*): Expected concentrations of thiacloprid metabolite Z5 in percolate water considering intended application rates and plant interception. Bayer AG, Report No. MR-093/02, date: 2002-02-27 - Stupp, H. P. (2002b *[Addendum I: 2002d]*): Formation and identification of metabolites of YRC2894 (e.g. Z5) in lysimeter soil. Bayer AG, Report No. MR-340/02, date: 2002-09-12. *Addendum I to PPP-Monograph; Chapter: B.8.2 Adsorption, desorption and mobility in soil. B.8.2.2 Case on the levels of lysimeter leachate component ascribed as Z5 (previously of unknown identity) and details of its characterisation [Evaluation table point 2.2] (Study 1)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; German BBA guidelines (Part IV, 4-2) "Aged column leaching study"	
2.2	**GLP**	[redacted]	X
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		A three-year (May 1994-December 1997) lysimeter study investigated leaching of YRC 2894 (thiacloprid) following applications in two successive years to a grass cover in accordance with BBA guidelines (Part IV, 4-3). Although grass is not a proposed use for YRC 2894, the grass cover was chosen to reflect a realistic worst-case situation for the worst-case proposed use (pome fruits). Other uses such as those on fruiting vegetables do not include repeated applications in successive years.	X
		Undisturbed cores (surface area 1 m^2, depth 1.25 m) of a sandy loam over sand (texture according to USDA, topsoil pH 7.0, 1.41% oc) were	

buried on a lysimeter facility at Monheim, Germany in 1993. Two lysimeters (A and B) were cropped with grass sown in April 1994 and 1995 and cultivated according to common agricultural practice (cuts to 8-10 cm when height reached 20-25 cm). The grass was incorporated into the subsoil in March 1995 and sown again in April 1995 to keep test conditions identical for the two years of application. Two post-emergence applications (total amount split into two equal treatments separated by a 15-day interval) of [14C]YRC 2894 were sprayed onto the two lysimeters (treated surface area 0.81 m^2) in May 1994 and May 1995 at total rates of 0.400 kg a.s./ha (1994) and 0.365 kg a.s./ha (1995). Formulations of YRC 2894 differed between the two years of application (SC 600 for the first year, SC 480 for the second). Other pesticide and fertilisers were also applied to the lysimeters according to normal agricultural practice.

Leachate was collected from the base of each lysimeter in 1- to 56-litre batches at 1- to 12-week intervals. Total radioactivity in samples of each batch was quantified by LSC and dissolved [14C]CO_2 was quantified by LSC after acidification and expulsion with nitrogen. At all sampling intervals, 10% of the leachate sample was filled into a stainless steel container to continuously feed an annual mixed leachate sample. Annual mixed samples and selected individual samples were passed through solid phase extraction cartridges after acidification and addition of NaCl and the radioactivity eluted with methanol or acidified methanol was quantified by LSC and identified by TLC, using authentic standards and for confirmation purposes LC-MS and LC-MS/MS. Results were expressed as net radioactivity (measured by LSC after acidification), which is equivalent to the total radioactivity in the leachate minus dissolved [14C]carbonates.

4 RESULTS

At the end of the leachate sampling period, the soil was removed in 10-cm layers down to a depth of 40 cm (50 cm in the study protocol). For the remaining 40-120 cm, replicated soil cores (8 cm in diameter for 40-100 cm, 5 cm in diameter for 100-120 cm) were augered and later sectioned in 10-cm increments. All soil samples were air dried, mixed and radioactivity from aliquots was quantified by combustion/LSC. For samples to 40-cm depth, radioactivity was identified by TLC after extraction (two methanol/water extractions by Soxtec at 190°C) and concentration (for 20-30 and 30-40 cm samples only).

Total precipitation (rainfall + irrigation) was 889, 794 and 923 mm for the 1st, 2nd and 3rd years, respectively (Table A7_2_3_2-1). Although natural rainfall was below targets from October to December 95 (*i.e.* 2nd year), no supplementary irrigation was provided. A deficit in precipitation of *ca.* 115 mm accumulated which could not be readily compensated in January 96 due to frost and low precipitation. Compensation was eventually gained through heavy irrigation (9 to 15 mm events) in March and April 1996 (135 and 110 mm, respectively. Mean monthly air temperatures ranged from -1.2°C (January 1997) to

22.6°C (July 1994).

Similar total volumes of leachate were collected from the two lysimeters for the three successive years (ca. 415, 350 and 350 mm for year 1, 2 and 3, respectively). Results for total radioactive residues recovered in the leachate are shown in Figure A7_2_3_2-1. For all samples, negligible dissolved [14C]carbonates were recovered. Radioactivity in leachate at the end of the study period was 1.3 µg a.s. equivalent/litre. Results from the identification of leachate radioactivity are presented in Table A7_2_3_2-2. The total radioactivity in the table was determined on the basis of analysis of all individual samples of leachate whereas metabolite concentrations were determined from a composite sample comprising 10% sub-samples of all individual samples. For this reason, the sum of the concentrations of individual components may not equal the total residue concentration. Neither YRC 2894 nor the amide metabolite M02 were identified in any leachate sample. Three metabolites (M30, M34 and unknown metabolite Z5) were identified in leachate with at least one annual concentration exceeding 0.1 µg/l (maximum of 6.92 µg/l for M30). Other unidentified metabolites accounted for >0.1 µg/l when considered together, but for <0.1 µg/l when considered individually.

The total amount of radioactivity recovered from the soil was 56% AR. The predominant fraction of recovered radioactivity was located in the upper 20 cm of the soil core, but extractability was limited to 20% AR in this section. The quantities of the four metabolites which were identified in the top four soil segments are presented in Table A7_2_3_2-3. The amide M02 and M29 (YRC 2894 thiazolidinimine) were not found in leachate, but were identified in the soil.

Recalculations of Schafer (2002b) and Stupp (2002d):

The notifier proposes that as the most important processes for leaching of active substances and metabolites are degradation and adsorption and these processes are of a nearly linear nature (first order degradation and Freundlich adsorption exponents of approximately 0.9), there is likely to be a nearly linear relationship between the applied amount and concentrations of pesticides and metabolites in the percolate. Taking into account the applied amount of parent thiacloprid to the soil in the study and the intended uses, the notifier estimates that in practice the annual average concentration in the first year for Z5 would be 0.065µg/l compared to the 0.16 µg/l quantified in the experiment.

Section A7.2.3.2 **Mobility in at least three soil types and where relevant mobility of metabolites and degradation products (2)**

Annex Point IIIA XII 1.3

5 CONCLUSION

5.1 Conclusion

The overall recovery was 59% on average for the two lysimeters (soil 56% AR, leachate 3% AR, grass <0.05% AR). Remaining radioactivity was assumed to be lost via mineralisation of YRC 2894 in soil. X

In the annual mean concentrations thiacloprid was not detected in soil or leachate. The metabolites M30, M34 and Z5 and M32 (the last two with <10 µg/l) were found in leachate. In soil the following metabolites were identified: M29, M30, M02, M32 (last one with < 10 µg/l).

[redacted]

5.1.1 Reliability

[redacted] X

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 03/08/2006

Materials and Methods [redacted]

Results and discussion [redacted]

Conclusion [redacted]

Reliability [redacted]

Acceptability [redacted]

Remarks [redacted]

COMMENTS FROM ...

Date *Give date of comments submitted*

Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_2_3_2-1 Monthly sums of rainfall and irrigation (mm)

Month	Monthly rainfall	Monthly irrigation	Sum of rainfall and irrigation	Long-term mean (1966-90)
May 94	50.0	-	50.0	72
Jun. 94	66.6	-	66.6	77
Jul. 94	20.5	30.0	50.5	74
Aug. 94	67.4	45.0	112.4	71
Sep. 94	90.0	-	90.0	57
Oct. 94	56.4	-	56.4	53
Nov. 94	59.2	-	59.2	64
Dec. 94	68.1	-	68.1	68
Jan. 95	126.8	-	126.8	62
Feb. 95	90.1	-	90.1	43
Mar. 95	77.7	-	77.7	56
Apr. 95	41.4	-	41.4	46
1st year	814.2	75.0	889.2	743
May 95	49.4	-	49.4	72
Jun. 95	70.4	10.0	80.4	77
Jul. 95	70.0	33.0	103.0	74
Aug. 95	19.4	-	19.4	71
Sep. 95	86.1	-	86.1	57
Oct. 95	29.9	-	29.9	53
Nov. 95	40.7	-	40.7	64
Dec. 95	50.4	-	50.4	68
Jan. 96	7.4	-	7.4	62
Feb. 96	45.9	10.0	55.9	43
Mar. 96	17.7	135.0	152.7	56
Apr. 96	8.8	110.0	118.8	46
2nd year	496.1	298.0	794.1	743
24 months	1310.3	373.3	1683.3	1486
May 96	74.2	6.0	80.2	72
Jun. 96	28.8	65.0	93.8	77
Jul. 96	56.6	18.0	74.6	74

Aug. 96	138.3	-	138.3	71
Sep. 96	33.6	-	33.6	57
Oct. 96	83.7	-	83.7	53
Nov. 96	63.9	-	63.9	64
Dec. 96	38.2	-	38.2	68
Jan. 97	2.7	-	2.7	62
Feb. 97	85.9	18.0	103.9	43
Mar. 97	31.5	-	31.5	56
Apr. 97	60.0	30.0	90.0	46
3rd year	697.4	137.0	834.4	743
36 months	2007.7	510.0	2517.7	2199

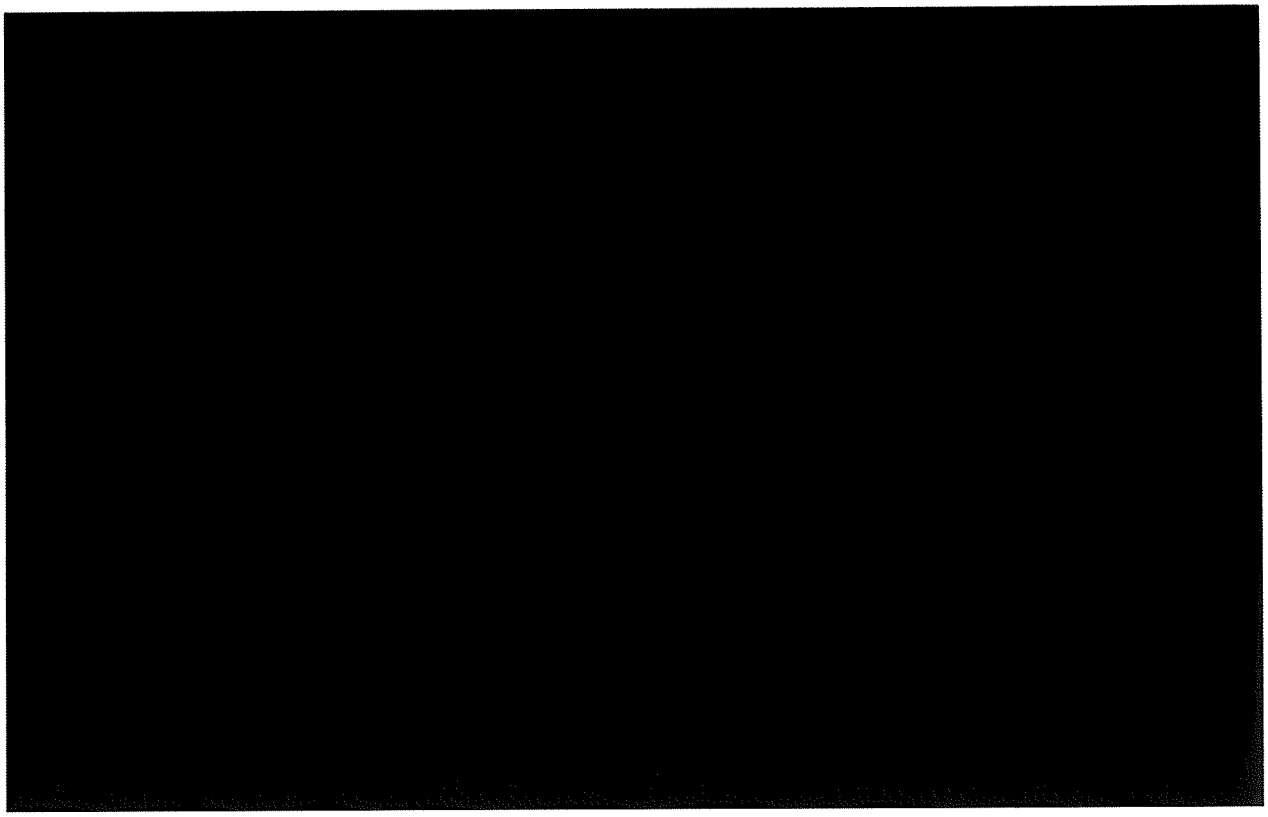
Table A7_2_3_2-2 **Identification of radioactivity from the leachate (all average concentrations in µg/l or µg a.s. equivalent/litre for non-identified metabolites; peaks are individual samples, annual means are the average of both lysimeters)**

	Concentrations in leachate							
	Total	Thiacloprid	M02	M30	M34	Z5	M32	Unidentified
Year 1								
Peak								
Annual mean								
Year 2								
Peak								
Annual mean								
Year 3								
Annual								
3-year average								

Table A7_2_3_2-3 **Identification of radioactive soil residues at the end of the experiment. All concentrations expressed in µg metabolite/kg except for the extracted and unknown metabolites expressed in µg a.s. equivalent/kg, and in % AR)**

	Extracted		Thiacloprid	M29		M30		M02		M32		Unknown	
	µg/kg	%AR		µg/kg	%AR	µg/kg	%AR	µg/kg	%AR	µg/kg	%AR	µg/kg	%AR
0-10 cm													
10-20 cm													
20-30 cm													
30-40 cm													
Total													

Figure A7_2_3_2-1 **Net radioactivity recovered in the leachate (expressed as µg/l of a.s. equivalent). The two applications were split into two applications (two-week interval). Day 0 is 17 May 1994**



Section A7.3.1

Annex Point: IIIA VII.5

Phototransformation in air (estimation method), including identification of breakdown products (1)

			Official use only
		1 REFERENCE	
1.1	**Reference**	Dr. Knoell Consult (2005): Calculation of indirect photodegradation of thiacloprid. *Not included in the PPP-Monograph. Test was performed as a requirement of the biocide products directive.*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	n.a., calculation	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		A theoretical calculation of the potential for photo-oxidation of thiacloprid was carried out using the software programme AOPWIN of the US-EPA, v. 1.91 (2000). The half-life was calculated based on an OH-radical concentration of 0.5 x 10^6 per cm^3 as an average for the 24 hours of the day.	
		4 RESULTS	
		A rate constant of 8.9×10^{-11} cm^3/molecules sec for hydroxyl radicals was calculated, which corresponds to a half-life in the upper atmosphere of 4.313 hours.	
		5 CONCLUSION	
5.1	**Conclusion**	The photodegradation half-life of thiacloprid in the air caused by indirect photodegradation was estimated to be significantly less than one day.	
5.1.1	Reliability	[redacted]	

Section A7.3.1
Annex Point: IIIA VII.5

Phototransformation in air (estimation method), including identification of breakdown products (1)

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	1/9/2006
	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.3.2 Annex Point IIIA 12.3	Fate and behaviour in air, further studies	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [X]	**Other justification** [ ]	
Detailed justification:	There were no further studies submitted on the fate and behaviour in air. Due to the very low vapour pressure of thiacloprid, air is not a relevant compartment for the active.	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	10/08/2006	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	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 A7.4.1.1 Acute toxicity to fish (1)

Annex Point IIA VII.7.1 *Oncorhynchus mykiss*

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] 1995a): YRC 2894 techn.: acute toxicity (96 hours) to rainbow trout (*Oncorhynchus mykiss*) in a static test [redacted] Report No [redacted] 95004, date: 1995-04-11, *revised 1998-09-25.* *PPP-Monograph Chapter: B.9.2 Effects on aquatic organisms. B.9.2.1 Acute toxicity (Table 9.7_Study 1)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, US-EPA FIFRA 72-1 and OECD guideline 203	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	X
		3 MATERIALS AND METHODS	
		The acute toxicity of thiacloprid (purity [redacted]% in DMF solvent) to 20 Rainbow trout (*Oncorhynchus mykiss*, mean body length 4.4 cm, mean body weight 1.2 g) was studied for 96 h under static test conditions to mean measured concentrations ranged from 4.85 to 37.4 mg as/L.	X
		4 RESULTS	
		The average mean measured concentrations of test solutions were between 93-96 % of nominal, and measured concentrations were used for the determination of the toxicological data. Based upon mean measured concentrations, the 96h-LC_{50} was determined to be 30.5 mg ai/l (95% confidence limits: 27.0-34.1). Based upon mean measured concentrations, the 96h-NOEC was determined to be < 4.99 mg ai/l. At the lowest test level (4.99 mg/l) all fish had darkened coloration and an abnormally low level of activity.	
		5 CONCLUSION	
5.1	**Conclusion**	[redacted]	X
5.1.1	Reliability	[redacted]	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	13/11/06
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.4.1.1 Acute toxicity to fish (2)

Annex Point IIA VII.7.1 *Lepomis macrochirus*

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted]1995b): YRC 2894 techn.: acute toxicity (96 hours) to bluegill (*Lepomis macrochirus)* in a static test [redacted] Report No. [redacted]5003, date: 1995-08-20. *PPP-Monograph Chapter: B.9.2 Effects on aquatic organisms, B.9.2.1 Acute toxicity (Table 9.7_Study 2)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; OECD guideline 203	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	X
		3 MATERIALS AND METHODS	
		The acute toxicity of thiacloprid (purity [redacted] % in DMF solvent) to 20 Bluegill Sunfish (*Lepomis macrochirus*, mean body length 3.1 cm, mean body weight 0.7 g) was studied for 96 h under static test conditions to mean measured concentrations ranged from 6.0 to 47.4 mg as/L in DMF solvent.	X
		4 RESULTS	
		The average mean measured concentrations of test solutions were between 93-97 % of nominal, and measured concentrations were used for the determination of the toxicological data.	X
		Based upon mean measured concentrations, the 96h-LC_{50} was determined to be 25.2 mg ai/l (95% confidence limits: 16.7-48.7).	
		Based upon mean measured concentrations, the 96h-NOEC was determined to be <6.20 mg ai/l. At 6.20 mg a.s./l (the lowest test level), all fish had darkened coloration.	
		5 CONCLUSION	
5.1	**Conclusion**	[redacted]	X
5.1.1	Reliability	[redacted]	

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 13/11/06

Materials and Methods

[redacted]

Results and discussion

[redacted]

Conclusion

[redacted]

Reliability

[redacted]

Acceptability

[redacted]

Remarks

[redacted]

COMMENTS FROM ...

Date *Give date of comments submitted*

Materials and Methods *Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.*
Discuss if deviating from view of rapporteur member state

Results and discussion *Discuss if deviating from view of rapporteur member state*

Conclusion *Discuss if deviating from view of rapporteur member state*

Reliability *Discuss if deviating from view of rapporteur member state*

Acceptability *Discuss if deviating from view of rapporteur member state*

Remarks

Section A7.4.1.1 Acute toxicity to fish (3)

Annex Point IIA VII.7.1 **Metabolite M02**

Oncorhynchus mykiss

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] 1998): Acute toxicity of KKO 2254 to the rainbow trout (*Oncorhynchus mykiss*) under static conditions [redacted] Report No. 107943, date: 1998-01-08. *PPP-Monograph Chapter: B.9.2 Effects on aquatic organisms. B.9.2.1 Acute toxicity (Table 9.8_Study 1)*	X
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, US-EPA FIFRA 72-1	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	X
		3 MATERIALS AND METHODS	
		The acute toxicity of the metabolite M02 (purit[redacted]%) to 10 Rainbow trout (*Oncorhynchus mykiss*, mean body length 3.2 cm, mean body weight 0.4 g) was studied for 96 h under static test conditions to one nominal concentration 79.4 mg test substance/L (limit test).	
		4 RESULTS	
		Based on the results of this test the NOEC of M02 exposed to Rainbow Trout was 79.4 mg test substance/L. Therefore the nominal LC_{50} was reported to be > 79.4 mg/l.This is a measured concentration. In average the recovery rates of nominal concentrations throughout the test were in the range of 98.8-99.6 %.	
		5 CONCLUSION	
5.1	**Conclusion**	The metabolite M02 is less toxic to fish than the active substance thiacloprid.	X
		[redacted]	
5.1.1	Reliability	[redacted]	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	13/11/06
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.4.1.1 **Acute toxicity to fish (4)**

Annex Point IIA VII.7.1 **Metabolite M02**

Lepomis macrochirus

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] 1997a *[Monograph: 1997]*): Acute toxicity o[redacted] o the bluegill (*Lepomis macrochirus*) under static conditions: [redacted] Report No. 107746; date: 1997-06-30. *PPP-Monograph Chapter: B.9.2 Effects on aquatic organisms. B.9.2.1 Acute toxicity (Table 9.8_Study 2)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, US-EPA FIFRA 72-1	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		The acute toxicity of the metabolite M02 (purity [redacted]%) to 10 Bluegill Sunfish (*Lepomis macrochirus*, mean body length 3.5 cm, mean body weight 1.1 g) was studied for 96 h under static test conditions to one mean measured concentration of 78.6 mg test substance/L (limit test).	
		4 RESULTS	
		Based on the results of this test the NOEC of M02 exposed to Bluegill Sunfish was 78.6 mg test substance/L. There were 2 mortalities out of 30 fish (6.7 % mortality) at this concentration. Thus, the LC_{50} was reported to be > 78.6 mg/l.This is a measured concentration. In average the recovery rates of nominal concentrations throughout the test were in the range of 95.4-99.8 %.	
		5 CONCLUSION	
5.1	**Conclusion**	The metabolite M02 is less toxic to fish than the active substance thiacloprid. [redacted]	X
5.1.1	Reliability	[redacted]	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	13/11/06
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.4.1.1 Acute toxicity to fish (5)

Annex Point IIA VII.7.1 **M30**

Oncorhynchus mykiss

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] 1995c): YRC 2894 - sulfonic acid - acute toxicity (96 hours) to rainbow trout (*Oncorhynchus mykiss*) in a static test [redacted] Report No [redacted] 5051, date: 1995-09-26. *PPP-Monograph Chapter: B.9.2 Effects on aquatic organisms. B.9.2.1 Acute toxicity (Table 9.9_Study 1)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, OECD guideline 203	
2.2	**GLP**	Yes	
2.3	**Deviations**	None	
		3 MATERIALS AND METHODS	
		The acute toxicity of the metabolite M30 (purity [redacted] %) to rainbow trout (*Oncorhynchus mykiss*,, mean body length 3.7 cm, mean body weight 0.5 g) was studied for 96 h under static test conditions to one nominal concentration 90.1 mg test substance/L (limit test) for 10 fish.	X
		4 RESULTS	
		Based on the results of this test the 48h-NOEC of M30 exposed to Rainbow Trout was 90.1 mg test substance/L. Therefore the nominal 48h-LC_{50} is greater than > 90.1 mg/l. The recovery rate of the initial concentration was reported to be 99.3 %.	X
		5 CONCLUSION	
5.1	**Conclusion**	The metabolite M30 is less toxic to fish than the active substance thiacloprid.	X
		[redacted]	
5.1.1	Reliability	[redacted]	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	13/11/06
Materials and Methods	[redacted]
Results and discussion	Reported as in the monograph for the Plant Protection Products Directive with the [redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.4.1.2 Acute toxicity to invertebrates (1)

Annex Point IIA VII.7.2 *Daphnia magna* (crustacean)

			Official use only
		1 REFERENCE	
1.1	**Reference**	Heimbach, F. (1995a *[Monograph: 1995b]*): Acute toxicity of YRC 2894 (techn.) to water fleas (*Daphnia magna*). Bayer AG, Report No. HBF/Dm 141, date: 1995-05-16. *PPP-Monograph Chapter: B.9.2 Effects on aquatic organisms. B.9.2.1 Acute toxicity (Table 9.7_Study 3)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, OECD guideline 202	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		The acute toxicity of thiacloprid (tech., purity: [redacted] % in DMF solvent) to *Daphnia magna* (1st instars < 24 h old) was studied in a static test system. Water fleas were exposed for 48 h to cconcentrations (mean measured) ranging from 1.05 to 85.1 mg as/L. No higher concentrations could be tested, because of the solubility of the as in water.	X
		4 RESULTS	
		The average mean measured initial concentrations of test solutions were between 85.1-105.0 % of nominal. Measured concentrations were used for the determination of the toxicological data. Based upon mean measured concentrations, both 24h-EC_{50} and 48h-EC_{50} was determined to be > 85.1 mg ai/l (95% confidence limits: not calculable). At this (the highest) test concentration 20 % immobilisation was observed. White precipitate observed at this test concentration. No such precipitation seen at the 48.3 mg a.s./l test level, at which 23% immobilisation was observed. The 96h-NOEC, based on mean measured concentrations, was reported to be 9.10 mg/l.	X

Section A7.4.1.2 Acute toxicity to invertebrates (1)

Annex Point IIA VII.7.2 *Daphnia magna* (crustacean)

		5 CONCLUSION	
5.1	Conclusion	[redacted]	X
5.1.1	Reliability	[redacted]	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	13/11/06
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*

Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.4.1.2 Acute toxicity to invertebrates (2)

Annex Point IIA VII.7.2 *Hyalella azteca* (crustacean)

			Official use only
		1 REFERENCE	
1.1	**Reference**	Bowers, L. (1996): Acute toxicity of YRC 2894 to *Hyalella azteca* under static conditions. Bayer AG, Report No. 107336, date: 1996-06-24. *PPP-Monograph Chapter: B.9.2 Effects on aquatic organisms. B.9.2.1 Acute toxicity (Table 9.7_Study 4)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, US-EPA FIFRA 72-2	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		The acute toxicity of thiacloprid (tech., purity: [redacted] %) to 20 *Hyalella azteca* (0.4 mm head length; 14 - 21 days old at initiation) was studied in a static test system in duplicate. Water fleas were exposed for 96 h to mean measured concentrations of 0.006, 0.011, 0.024, 0.045 and 0.091 mg as /l.	X
		4 RESULTS	
		The average mean measured initial concentrations of test solutions were between 90-101 % of nominal, but measured concentrations were used for the determination of the toxicological data.	
		Based upon mean measured concentrations, the 96h-EC_{50} for the endpoint immobility was determined to be 0.0407 mg ai/l (95 % confidence limits: 0.0310-0.0565). The EC_{50} which also took account of the number of 'floaters' at the surface (a sublethal parameter) was 0.0245 mg a.s./l.	X
		Additionally, the 96h-NOEC, based on mean measured concentrations, was reported to be 0.01133 mg/l.	

Section A7.4.1.2 Acute toxicity to invertebrates (2)

Annex Point IIA VII.7.2 *Hyalella azteca* (crustacean)

		5 CONCLUSION	
5.1	**Conclusion**	[redacted]	X
5.1.1	Reliability	[redacted]	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	13/11/06
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*

Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.4.1.2	**Acute toxicity to invertebrates (3)**	
Annex Point IIA VII.7.2	**M02**	
	Hyalella azteca (crustacean)	

			Official use only
		1 REFERENCE	
1.1	**Reference**	Bowers, L.M. (1997b *[Monograph: 1997]*): Acute toxicity of KKO 2254 to *Hyalella azteca* under static conditions. Bayer AG, Report No. 107719, date: 1997-06-18. *PPP-Monograph Chapter: B.9.2 Effects on aquatic organisms. B.9.2.1 Acute toxicity (Table 9.8_Study 3)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, US-EPA FIFRA 72-2	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		The acute toxicity of the metabolite M02 (tech., purity: [redacted]%) to 20 *Hyalella azteca* (0.22 mm head length; 14 - 21 days old at initiation) per test concentration was studied in a static test system in duplicate in the definitive test. Water fleas were exposed for 96 h to mean measured concentrations of 2.52, 5.55, 12.0, 23.9 and 47.6 mg M02 /l.	
		4 RESULTS	
		The average mean measured initial concentrations of test solutions were between 81-96 % of nominal, but measured concentrations were used for the determination of the toxicological data. Based upon mean measured concentrations, the 96h-EC_{50} was determined to be > 47.6 mg ai/l (95% confidence limits: no calculable). Based upon mean measured concentrations, the 96h-NOEC was determined to be 5.55 mg ai/l. This NOEC is based on effects on behaviour (i.e. sublethal parameters) at ≥ 12.0 mg/l. No mortality (immobility) was observed at any test level (highest test concentration: 47.6 mg/l).	

		5 CONCLUSION	
5.1	**Conclusion**	The metabolite M02 is considerably less toxic to aquatic than the active substance thiacloprid.	X
		[redacted]	
5.1.1	Reliability	[redacted]	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	13/11/06
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.4.1.2 Acute toxicity to invertebrates (4)

Annex Point IIA VII.7.2 **M30**

Daphnia magna (crustacean)

			Official use only
		1 REFERENCE	
1.1	**Reference**	Heimbach, F. (1995b *[Monograph: 1995c]*): Acute toxicity of YRC 2894 – sulfonic acid to waterfleas (*Daphnia magna*). Bayer AG, Report No. HBF/Dm 152, date: 1995-02-16. *PPP-Monograph Chapter: B.9.2 Effects on aquatic organisms. B.9.2.1 Acute toxicity (Table 9.9_Study 2)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, OECD guideline 202 and US-EPA FIFRA 72-2	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		The acute toxicity of the metabolite M30 (tech., purity: [redacted] %) to *Daphnia magna* (1st instars < 24 h old) was studied in a static test system. Water fleas were exposed for 96 h to measured concentrations of 0.97, 3.25, 9.6, 17.4, 32.1, 65.4 and 96.1 mg ai/l.	
		4 RESULTS	
		The average mean measured initial concentrations of test solutions were between 96-101 % of nominal. Measured concentrations were used for the determination of the toxicological data.	X
		Based on the results of this test the NOEC of M30 exposed to Daphnia magna was 100 mg test substance/L. Therefore the measured LC_{50} is determined to be greater than 100 mg/l.	
		5 CONCLUSION	
5.1	**Conclusion**	The metabolite M30 is less toxic than the active substance thiacloprid.	X
		[redacted]	
5.1.1	Reliability	[redacted]	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	13/11/06
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.4.1.2	Acute toxicity to invertebrates (5)
Annex Point IIA VII.7.2	*Asellus aquaticus* (freshwater hog louse, crustacean)

		1 REFERENCE	Official use only
1.1	**Reference**	Manson, P.S. (2002a): Thiacloprid: Acute toxicity to *Asellus aquaticus*. COVANCE Ltd., North Yorkshire, England. Bayer AG, Report No. 262/141, date: 2002-09-24. *Addendum I to PPP-Monograph; Chapter: B.9.2 Surface water. B.9.2.2 Microcosm and mesocosm studies - c) Additional species data (Study 1)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X

		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, OECD guideline 202	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	X

	3 MATERIALS AND METHODS	
	A 48-hour static study without renewal was undertaken with the test organism *Asellus aquaticus* (freshwater hog louse) with thiacloprid [redacted]% purity). The nominal concentrations tested were 0.009, 0.019, 0.041, 0.09 and 0.20 mg a.s./l. There were 10 replicates for the control and each of the test concentrations with one *A. aquaticus* per vessel. Numbers of dead and immobilised *A. aquaticus* were monitored after 3, 24 and 48 hours. Temperatures were maintained at approximately 13 °C and the pH was within the range 7.0 to 8.5 with only minor deviations.	X

	4 RESULTS	
	Measured concentrations of thiacloprid at the start and end of the test period were 93-94% of nominals. The 48 hour LC_{50} value based on mortality was 0.0989 mg a.s./l and the EC_{50} value for mortality and immobility was 0.0758 mg a.s./l based on nominal concentrations (95% confidence limits for these values could not be calculated). The lowest concentration causing 100% mortality was 0.20 mg a.s./l and the NOEC was 0.041 mg a.s./l.	X

5 CONCLUSION

5.1	**Conclusion**	[redacted]	X
5.1.1	Reliability	[redacted]	X

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	13/11/06
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*

Section A7.4.1.2	Acute toxicity to invertebrates (5)
Annex Point IIA VII.7.2	*Asellus aquaticus* (freshwater hog louse, crustacean)

Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

			Official use only
		1 REFERENCE	
1.1	**Reference**	Manson, P.S. (2002b): Thiacloprid: Acute toxicity to larvae of *Sericostoma personatum* (caddis fly). COVANCE Ltd., North Yorkshire, England. Bayer AG, Report No. 262/140, date: 2002-09-24. *Addendum I to PPP-Monograph; Chapter: B.9.2 Surface water. B.9.2.2 Microcosm and mesocosm studies - c) Additional species data (Study 2)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, OECD guideline 202	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		A 48-hour static study without renewal was undertaken with the test organism *Sericostoma personatum* (caddis fly) with thiacloprid ([redacted]% purity). The nominal concentrations tested were 0.001, 0.01, 0.1 and 1.0 mg a.s./l. There were 3 replicates for the control and 0.001 mg a.s./l treatment and four replicates for the 0.01, 0.1 and 1.0 mg a.s./l treatments with one caddis fly per vessel. After approximately 48 hours vessels were observed for immobile *S. personatum* and where none was seen in the case it was opened and assessed for immobility.	X
		4 RESULTS	
		After 48 hours there was a 75% effect (3 out of 4 larvae) at 1.0 mg a.s./l, 0% effect at 0.1 mg a.s./l, 25% effect at 0.01 mg a.s./l and 33% effect at 0.001 mg a.s./l. The 48 hour EC_{50} value for immobility was observed to be between 0.1 and 1.0 mg a.s./l. It is important to note that there was no chemical analysis of the thiacloprid concentrations. Also the variability in the dose response relationship should be noted. A definitive test could not be performed due to difficulties in obtaining further test organisms at the time.	
		5 CONCLUSION	
5.1	**Conclusion**	[redacted]	X

5.1.1 Reliability [redacted] X

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	20/07/06
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.4.1.2 Acute toxicity to invertebrates (7)

Annex Point IIA VII.7.2 *Gammarus pulex* (freshwater shrimp, crustacean)

			Official use only
		1 REFERENCE	
1.1	**Reference**	Manson, P.S. (2002c): Thiacloprid: Acute toxicity to *Gammarus pulex*. COVANCE Ltd., North Yorkshire, England. Bayer AG, Report No. 262/142, date: 2002-09-24. *Addendum I to PPP-Monograph; Chapter: B.9.2 Surface water, B.9.2.2 Microcosm and mesocosm studies - c) Additional species data (Study 4)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, OECD guideline 202	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	X
		3 MATERIALS AND METHODS	
		A 48-hour static study without renewal was undertaken with the test organism *Gammarus pulex*. (freshwater shrimp) with thiacloprid ([redacted]% purity). The nominal concentrations tested were 0.004, 0.009, 0.019, 0.041, 0.09 and 0.20 mg a.s./l. There were 10 replicates for the control and each of the test concentrations with one *G. pulex* per vessel. Numbers of dead and immobilised *G. pulex* were monitored after 3, 24 and 48 hours. Temperatures were maintained at approximately 13 °C and the pH was within the range 6.9 to 8.4.	X
		4 RESULTS	

Section A7.4.1.2 Acute toxicity to invertebrates (7)

Annex Point IIA VII.7.2 *Gammarus pulex* (freshwater shrimp, crustacean)

	Measured concentrations of thiacloprid at the start and end of the test period were 88-95% of nominals. Results were based on nominal concentrations. The 48-hour LC_{50} value based on mortality was 0.056 mg a.s./l (95% confidence limits 0.035-0.098) and the EC_{50} value for immobility was 0.068 mg a.s./l (95% confidence limits 0.043-0.117). The 48-hour EC_{50} value for combined mortality and immobility was 0.027 mg a.s./l (95% confidence limits 0.018 – 0.042 mg a.s./l). No effects >10% were observed in any of the concentrations after 24 hours and the 24 hr NOEC was 0.20 mg a.s./l. After 48 hours effects of above 10% were observed at concentrations of 0.019 mg a.s./l and above and the 48 hr NOEC was 0.009 mg a.s./l. The lowest concentration causing 100% mortality was 0.20 mg a.s./l.	X
	5 CONCLUSION	
5.1 Conclusion	[redacted]	X
5.1.1 Reliability	[redacted]	X

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	20/07/06
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Remarks	**1.2.3** This should read: Data submitted on new a.s. for the purpose of its entry into [redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.4.1.2 Acute toxicity to invertebrates (8)

Annex Point IIA VII.7.2 *Ecydonurus sp.* (mayfly larvae)

			Official use only
		1 REFERENCE	
1.1	**Reference**	Manson, P.S. (2002d): Thiacloprid: Acute toxicity to mayfly larvae. COVANCE Ltd., North Yorkshire, England. Bayer AG, Report No. 262/144, date: 2002-09-24. *Addendum I to PPP-Monograph; Chapter: B.9.2.2 Surface water. Microcosm and mesocosm studies - c) Additional species data (Study 2)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; OECD guideline 202	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	X
		3 MATERIALS AND METHODS	
		A 48-hour static study without renewal was undertaken with the test organism *Ecydonurus sp.* (mayfly larvae) with thiacloprid ([redacted]% purity). The nominal concentrations tested were 0.004, 0.009, 0.019, 0.041 and 0.09 a.s./l. There were 10 replicates for the control and each of the test concentrations with one *mayfly* per vessel. Numbers of dead and immobilised *Ecydonurus sp.* were monitored after 3, 24 and 48 hours. Temperatures were maintained at approximately 13 °C and the pH was within the range 6.7 to 7.6.	X
		4 RESULTS	
		Measured concentrations of thiacloprid at the start and end of the test period were 75-93% of nominals. Results were based on nominal concentrations. The 48 hour LC_{50} value based on mortality was 0.0238 mg a.s./l (95% confidence limits 0.0133-0.0468) and the EC_{50} value for mortality and immobility was 0.0077 mg a.s./l (95% confidence could not be calculated). The lowest concentration causing 100% effect (mortality and immobilisation) was 0.019 mg a.s./l and the highest concentration causing no effect was 0.004 mg a.s./l. Effects above 10% occurred in concentrations of 0.009 and above after 24 and 48 hours resulting in a NOEC of 0.004 mg a.s./l.	X
		5 CONCLUSION	
5.1	**Conclusion**	The study was well performed and reported, according to the test guideline for acute Daphnia toxicity, but using *Ecydonurus sp.* [redacted]	X
5.1.1	Reliability	[redacted]	X

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	08/01/2008 [redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*

Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.4.1.3 Growth inhibition test on algae (1)

Annex Point IIA VII.7.3 *Pseudokirchneriella subcapitata*

			Official use only
		1 REFERENCE	
1.1	**Reference**	Anderson, J.P.E. (1995a *[Monograph: 1995]*): Influence of YRC 2894 on the growth of the green alga, *Selenastrum capricornutum*. Bayer AG, Report No. AJO/129495, date: 1995-07-06. *PPP-Monograph Chapter: B.9.2 Effects on aquatic organisms. B.9.2.1 Acute toxicity (Table 9.7_Study 5)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; OECD guideline 201 and Directive 92/69/EEC method C.3	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	X
		3 MATERIALS AND METHODS	
		The acute toxicity of thiacloprid (tech., purity: [redacted]%) to *Pseudokirchneriella subcapitata* (formerly: *Selenastrum capricornutum*) was studied in a static test system for 120 h. The following nominal concentrations: 3.2, 5.6, 10.0, 18.0, 32.0, 56.0 and 100 mg/l were tested.	X
		4 RESULTS	
		For the endpoint growth rate an E_rC_{50} (120 h) of > 100 mg/l was determined. The endpoint biomass was more sensitive, as an E_bC50 of 60.6 mg/l (confidence limits not given) was obtained. Additionally, the NOEC for both endpoints was reported to be 18 mg/l. All concentrations are nominal. The average mean measured initial concentrations of test solutions were between 94.9-97.9 % of nominal, therefore nominal concentrations were used for the determination of the ecotoxicological data.	
		5 CONCLUSION	
5.1	**Conclusion**	[redacted]	X
5.1.1	Reliability	[redacted]	

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 13/11/06

Materials and Methods [redacted]

Results and discussion [redacted]

Conclusion [redacted]

Reliability [redacted]

Acceptability [redacted]

Remarks [redacted]

COMMENTS FROM ...

Date *Give date of comments submitted*

Materials and Methods *Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.*
Discuss if deviating from view of rapporteur member state

Results and discussion *Discuss if deviating from view of rapporteur member state*

Conclusion *Discuss if deviating from view of rapporteur member state*

Reliability *Discuss if deviating from view of rapporteur member state*

Acceptability *Discuss if deviating from view of rapporteur member state*

Remarks

Section A7.4.1.3 Growth inhibition test on algae (2)

Annex Point IIA VII.7.3 *Scenedesmus subspicatus*

			Official use only
		1 REFERENCE	
1.1	**Reference**	Anderson, J.P.E. (1995b *[Monograph: 1995]*): Influence of YRC 2894 on the growth of the green alga, *Scenedesmus subspicatus*. Bayer AG, Report No. AJO/132695, date: 1995-09-04. *PPP-Monograph Chapter: B.9.2 Effects on aquatic organisms. B.9.2.1 Acute toxicity (Table 9.7_Study 6)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; OECD guideline 201 and Directive 92/69/EEC method C.3	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	X
		3 MATERIALS AND METHODS	
		The acute toxicity of thiacloprid (tech., purity: [redacted]%) to *Scenedesmus subspicatus* was studied in a static test system for 72 h. The following concentrations of nominal: 10, 18, 32, 56, and 100 mg as/L were tested.	X
		4 RESULTS	
		For the endpoint growth rate an E_rC_{50} (72 h) of 96.7 mg/l was determined. The endpoint biomass was more sensitive, as an E_bC_{50} of 44.7 mg/l was obtained. Confidence limits for both were not given. Additionally, he NOEC for biomass and growth rate were determined to be < 10 mg/l and 32 mg/l respectively. All concentrations are nominal. The average mean measured initial concentrations of test solutions were between 96.7-106.2 % of nominal, therefore nominal concentrations were used for the determination of the ecotoxicological data.	
		5 CONCLUSION	
5.1	**Conclusion**	[redacted]	X
5.1.1	Reliability	[redacted]	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	13/11/06
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Remarks

Section A7.4.1.3 Growth inhibition test on algae (3)

Annex Point IIA VII.7.3 **M02**

Pseudokirchneriella subcapitata

			Official use only
		1 REFERENCE	
1.1	**Reference**	Dorgerloh, M. (1998): KKO 2254 - Influence on the growth of the green alga, *Pseudokirchneriella subcapitata.* Bayer AG, Report No. DOM 98055, date: 1998-08-24. *PPP-Monograph Chapter: B.9.2 Effects on aquatic organisms, B.9.2.1 Acute toxicity (Table 9.8_Study 4)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; OECD guideline 201 and Directive 92/69/EEC method C.3	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	X
		3 MATERIALS AND METHODS	
		The acute toxicity of thiacloprid (tech., purity: [redacted] %) to *Pseudokirchneriella* subcapitata (formerly *Selenastrum capricornutum*) was studied in a static test system for 96 h. The following nominal concentrations 10, 18, 32, 56, and 100 mg as/L were tested.	X
		4 RESULTS	
		The EC_{50} values for both endpoints growth rate and biomass were determined to be > 100 mg/l. The NOEC was 100 mg/l also for both endpoints. All concentrations are nominal. The 96 h EC_{50} and NOEC for cell density were >100 and 50 mg/l, respectively. The average mean measured initial concentrations of test solutions were between 94.8-103.4 % of nominal, therefore nominal concentrations were used for the determination of the ecotoxicological data.	
		5 CONCLUSION	
5.1	**Conclusion**	[redacted]	X
5.1.1	Reliability	[redacted]	X

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	13/11/06
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*

Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.4.1.3 Growth inhibition test on algae (4)

Annex Point IIA VII.7.3 **M30**

Scnedesmus subspicatus

			Official use only
		1 REFERENCE	
1.1	**Reference**	Anderson, J.P.E. (1996): Influence of YRC 2894-sulfonic acid on the growth of the green alga, *Scenedesmus subspicatus*. Bayer AG, Report No. AJO/130495, date: 1996-02-27. *PPP-Monograph Chapter: B.9.2 Effects on aquatic organisms. B.9.2.1 Acute toxicity (Table 9.9_Study 3)*	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; OECD guideline 201 and Directive 92/69/EEC method C.3	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	X
		3 MATERIALS AND METHODS	
		The acute toxicity of thiacloprid (tech., purity: [redacted] %) to *Scnedesmus subspicatus* was studied in a static test system for 72 h. The test was performed with only one concentration 100 mg/l (limit test).	X
		4 RESULTS	
		The EC_{50} values for both endpoints growth rate and biomass were both determined to be > 100 mg/l. The NOEC was 100 mg/l also for both endpoints. All concentrations are nominal. The measured concentration of the test solution was 97.6 % of nominal, therefore the nominal concentration was considered.	
		5 CONCLUSION	
5.1	**Conclusion**	[redacted]	X
5.1.1	Reliability	[redacted]	X

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	13/11/06
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*

Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.4.1.4 Inhibition to microbial activity (aquatic)

Annex Point IIA VII.7.4

			Official use only
		1 REFERENCE	
1.1	**Reference**	Müller, G. (1995): Studies on the ecological behaviour of YRC 2894. Bayer AG, Report No. 544A/95, date: 1995-09-21. Weyers, A. (2005): Re-evaluation based on study report 544 A/95 (Toxicity of YRC 2894 to bacteria), corresponding raw data and additional information provided by the sponsor. Bayer Industry Services GmbH & Co. OHG. Sponsored by LANXESS Deutschland GmbH. *PPP-Monograph Chapter: B.9.10 Effects on biological methods for sewage treatment – effects.* ***Cursive parts below are additions to the PPP Monograph made by the BPD applicant.***	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, ISO 8192; Commission Directive 88/302/EEC (Official Journal of the EG L 133) part C.11 (1988); generally corresponding to OECD guideline 209	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	X
		3 MATERIALS AND METHODS	
		In a study on YRC 2894 technical (thiacloprid, purity [redacted] %), activated sludge (mixed populations of different aquatic microorganisms received from the domestic sewage treatment plant of Odenthal in Germany) was exposed for 30 min to nominal concentrations ranging from 1000 to 10000 mg a.s./l.	X
		See Table 7_4_1_4-1 for details on inoculum. *Details of the test conditions are summarised in Table 7_4_1_4-2.* *A defined quantity of activated sludge was mixed with synthetic medium and respiratory rate was measured (two controls). This rate was compared to those measured in test preparations with various concentrations of the test substance. In order to check the sensitivity of the activated sludge used, 3,5-dichlorophenol was used as a reference substance.* *A range finding test for both the test substance and reference substance preceded a definitive test. The obtained information about the range of concentrations is used in the main test.* *The oxygen concentration was measured in the controls and in every concentration of the test substance and reference substance at the beginning and at the end of the test period. pH-value and temperature*	

Section A7.4.1.4 Inhibition to microbial activity (aquatic)

Annex Point IIA VII.7.4

were determined in the controls and in every test concentration of test and reference substance at the end of the test.

The test item and reference substance concentration are not confirmed by analytical methods; they are based on nominal concentrations.

The EC50 values for test substance and reference substance were determined by statistical methods (probit analysis). Concentration/effect *curves (inhibition vs. concentration) for test substance and reference substance are plotted in the original report.*

4 RESULTS

Respiratory rates and inhibitory effects (%) at the tested thiacloprid concentrations are given in Table 7_4_1_4-3.

The EC_{50} for respiration rate was 6330 mg a.s./l, indicating low bactericidal activity *(EC_{10} = 1340 mg/l, EC_{90} = 30000 mg/l).*

At nominal test concentrations of 1000 to 10000 mg/l, inhibition of respiration in activated sludge was observed between 16.7 % and 87.8 % (see Table A7_4_1_4-3).

No physico chemical oxygen consumption was determined at a test substance concentration of 10000 mg/l. Therefore lower concentrations of the test substance cause no physico chemical oxygen consumption (deduced values).

The toxicity of the reference substance 3,5-dichlorophenol to bacteria was characterized with an *EC50 value of 14 mg/l.*

5 CONCLUSION

5.1 Conclusion

The result suggests that thiacloprid has only low toxicity to activated sludge organisms; therefore there is no potential of damage of the selfpurification of water from a sewage treatment plant. X

All validity criteria of the test method (OECD 209) were met:
- respiratory rate of the two controls differs less than 15%
- respiratory rate of the controls is < 60 mg O_2/l·h
- EC_{50} of the reference substance 3.5-Dichlorophenol is in the range 5–30 mg/l

A dose – response relationship can be seen from the test.

[redacted]

5.1.1 Reliability

[redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14/11/06
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	