Table A7_4_1_4-1: Inoculum

Criteria	*Details*
Nature	*Activated sludge (mixed population of aquatic micro-organisms)*
Species	-
Strain	-
Source	*Waste water treatment plant treating domestic sewage*
Sampling site	*Aeration tank of the waste water treatment plant (Odenthal, Germany)*
Laboratory culture	*Yes*
Method of cultivation	*Culture medium: Stock solution containing peptone, meat extract, urea and mineral salts*
Preparation of inoculum for exposure	*-first, the sludge is settled and the supernatant is decanted* *-after centrifuging (15 min at 4500 rpm and 20 °C) the supernatant is decanted* *-1 g of the wet sludge is dried in order to calculate the amount of wet sludge to achieve a concentration of activated sludge of 2 g/l (dry wet) suspended solids* *-the calculated amount of sludge is first dissolved in synthetic medium and than filled up to a defined end volume with deionised water* *- storage of sludge: aeration of the activated sludge at 20 C ± 2 °C, daily feed with 50 ml of synthetic medium*
Pre-treatment	*None*
Initial cell concentration	-

Table A7_4_1_4-2: Test conditions

Criteria	*Details*
Test temperature	*20 ± 2 °C at the beginning, 20.3-21.4 °C, recorded at the end of the test*
pH	*8.0 (suspension before application of the main test)* *8.2 (suspensions with test substance at the end of the experiment). For the highest concentration tested a pH of 8.4 was measured.* *8.2 (control suspensions measured at the end of the experiment)* *7.3 (physico-chemical oxygen consumption control)*
Aeration of dilution water	*The test substance has been added to about 130 ml deionised water and stirred over 16.5 hours before testing (equilibration phase)*
Incubation time	*30 minutes*
Test substance concentrations	*0 (two controls), 1000, 1800, 3200, 5600 and 10000 mg/l;* *Test substance concentration in physico-chemical oxygen consumption control: 10000 mg/l*
Reference substance concentrations	*2.5, 5, 10, 20, 40 mg/l*
Method of application	*Direct weighing*
Suspended solids concentration (test concentration of the activated sludge)	*Inoculum concentration: 800 mg/l*

Table A7_4_1_4-3: Test results of test substance (based on nominal concentrations) and controls

Test Compound [mg/l]	*Respiratory Rate [mg O₂/l h]*	*Inhibition [%]*
1000	[redacted]	[redacted]
1800	[redacted]	[redacted]
3200	[redacted]	[redacted]
5600	[redacted]	[redacted]
10000	[redacted]	[redacted]

Control	*Respiratory rate [mg O₂/l·h]*
Control 1	*60.0*
Control 2	*60.0*

Section 7.4.2 **Annex Point IIA VII.7.5** **Section 7.4.3.3.1** **Annex Point IIIA XIII.2.3** **Section 7.4.3.3.2** **Annex Point IIIA XIII.2.3**	**Bioconcentration/Bio-accumulation in an appropriate species of fish/ Bio-accumulation in an appropriate invertebrate species**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X].**	
Detailed justification:	No study was submitted on bioaccumulation or bioconcentration in an aquatic organism (fish or invertebrate). According to the Technical Guidance Document, the measured log Kow according to OECD 107 and OECD 117 (log Pow = 1.26, log Pow = 0.73-0.74, respectively), indicates that thiacloprid has no bioaccumulation potential in aquatic organisms. According to these results there is no indication for further testing on bioaccumulation in aquatic organisms.	
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	08/08/06	
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 A7.4.3 Effects on aquatic organisms, further studies

Annex Point IIIA XIII.2 Microcosm study

			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. Additional letters response from Heimbach: Letter Response (dated 13 December 1999): COP 98/01202 – YRC 2894 (proposed name thiacloprid) Committee Stream Application. PSD-reference YPP 53/ASY 191. Technical Report No. ECO.040. Letter Response (dated 31 January 2000): Additional comments: Interpretation of the Ceratopogonidae data. *PPP-Monograph Chapter: B.9.2 Effects on aquatic organisms. B.9.2.2 Chronic toxicity - e) Microcosm and mesocosm 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**	No, internal method used	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		YRC 2894 SC 480 (a.s. thiacloprid, content [redacted]% w/w) was applied twice at 14 day intervals 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 thick (silty sand, 1.1% oc). Tanks were initially interconnected with an additional tank and water pumped between them 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 just expose the upper 30 cm i.e. to the depth of the water surface. The tanks were outside and exposed to climatic conditions. There was no replication of the treatments but there were three replicates for the controls. 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. The test substance was applied	X

at the beginning of the early growing season in May 1996 on day 0 and again on day 14. The test substance was sprayed on to the water surface using a commercial air assisted sprayer. After spraying the remaining dispersion in the sprayer was determined to calculate the exact volume applied. It was determined that between 99.7 and 99.6% of the intended dose respectively was applied on day 0 and 14.

Samples were taken at four pre-determined positions in the tank. Water was sampled using a water-proof vacuum cleaner, withdrawing approximately 7 l of water. Sediment samples were taken using a grab into the top 5 cm. Zooplankton were sampled by removing a 5 l sample from each sampling position and passing this across a mesh, prior to preservation. For analysis of the phytoplankton 0.5 l of the water sample was preserved. Emergence traps (0.25 m^2) to catch insect adults were placed in the centre of ponds and the organisms preserved. Benthic organisms were assessed by passing the grab sample taken from the top 5 cm of sediment through a mesh and preserving them. Macrophytes and periphyton algae were assessed visually. Two litre samples were used for the determination of physico-chemical parameters and chlorophyll$_a$.

4 RESULTS

Chlorophyll$_a$ content and turbidity X

The chlorophyll$_a$ content of the three control replicates were comparable throughout the study period. This was also true of all the treatments until day 56 when the level increased at the concentrations of 3.2 to 32 µg a.s./l. There was also a slight effect at 1.9 µg a.s./l. This was probably due to higher densities of periphyton algae at the higher concentrations. Turbidity data showed the controls and treatments to be comparable. Only at 5.6 µg a.s./l was there a large peak at day 56 and 77, however a similar peak was also observed in one of the controls at this time. It was considered that treatment did not impact on this parameter.

Indices used

The diversity of the microcosm community was measured using three different measures; Shannon-Weaver, Evenness and Standers Index. The Shannon-Weaver Index measures diversity and is dependent on both species richness and the frequency of distribution of the individuals of the species. The index increases with higher numbers of species and with increasing homogeneity of the number of individuals per species. It should be noted that a toxic effect can result in a decrease (due to the loss of a species or increase of dominance of a species) or increase of the Shannon-Weaver index (due to the decline of dominant species).

To compensate for the limitations of the Shannon-Weaver index a measure of Evenness was also used. This measure concentrates on the distribution of individuals to the species level and can be considered as an antagonist of the number of species. Evenness is calculated by dividing the Shannon-Weaver index by the maximum possible value.

This removes the influence of the number of species.

Standers index measures the relative abundances of single species within the community. A similarity index of 1.0 indicates an identical species composition between two samples while 0 indicates no correspondence.

EAC (Ecologically acceptable concentration)

The EAC has been defined by HARAP (Campbell et al. 1996) as the concentration at which the ecological function and community structure is not adversely affected. Effects are considered to be of low ecological relevance if recovery occurs during the study.

Residue analysis

Full details of the residue analysis during the course of the microcosm study are given in Section B 8.4.5. For convenience the most important points are reiterated here. 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. Peak concentrations during the study were measured on 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 is important to note 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. The peak concentrations on day 16 relative to the initial nominal concentrations are given in Table A7_4_3-1.

Emergence (of insect adults)

A total of 13 emergent insect genera were identified. These were Ephemeroptera, Odonata, Trichoptera and Nematocera. Nematocera were a major fraction in the microcosms. Total emergence increased with increasing test concentration. However, this was due to an increase in emergence of Chironomidae and a decrease in Chaoboridae and Ceratopogonidae. In the control these groups were present in approximately equal proportions. At 0.32 µg a.s./l the proportions of these species was comparable with the control. However, at 1.8 to 18 µg a.s./l Chironomids were the dominant genera with Chaoboridae and Ceratopogonidae at a total maximum of only 12%. At the highest test concentration the Nematocera composition was more balanced again, however there was a very low abundance at this concentration.

Data on the sum of emergence showed that natural fluctuations were between 0-25 animals/trap. After the first application there was only a decrease in emergence at 32 µg a.s./l. After the second application effects on emergence were observed and these are discussed in more detail. Low levels of Ephemeroptera in the 0.32 µg a.s./l concentration prior to day 14 meant that any effects at this concentration were difficult to see. The population remained at a low level for two months and then rapidly increased. At 0.56 to 1.8 µg a.s./l levels were reduced with recovery starting after day 77 (0.56 to 1.0 µg a.s./l) and day 84 at 1.8 µg

a.s./l. At higher concentrations no recovery was seen.

Levels of Nematocera showed similar results. There was little effect at 0.32 µg a.s./l, while at 0.56 to 3.2 µg a.s./l numbers were slightly reduced and increased after week 10. At 5.6 to 18 µg a.s./l there was a marked reduction in emergence with recovery only occurring at the end of the study. At the highest concentration (32 µg a.s./l) emergence numbers did not increase at the end of the study.

The numbers of Chironomidae were not affected up to 3.2 µg a.s./l. At 5.6 to 18 µg a.s./l there was an effect but numbers of emerged organisms increased at the end of the study. At 32 µg a.s./l there was no recovery during the course of the study.

Ceratopogonidae were the most sensitive taxon. A plot over time of the numbers of individuals/trap showed there was no effect at 0.32 µg a.s./l. At 0.56 µg a.s./l there was a slight reduction up to day 42 with recovery subsequently. The results at 1 µg a.s./l were very similar except for the last three weeks of the study. Results at concentrations in excess of 1 µg a.s./l showed that Ceratopogonidae larvae were able to survive and develop as the concentration of YRC 2894 declined with time (Table A7_4_3-2). The development time for these organisms is usually about a month under European conditions. The data showed that the concentration of the active substance fell below the toxic threshold level even for the highest doses a couple of weeks after the last application. Subsequent emergence in the study was dependent on the number of new eggs laid in the microcosms.

Since Ceratopogonidae were the most sensitive species the data were examined in more detail. These data show that at 0.56 and 1 µg a.s./l there is no difference in emergence up to day 70 with the actual numbers being 20 and 23 individuals per trap. From day 70 to day 98 at both 0.56 and 1 µg a.s./l the measured concentration was lower than in the earlier part of the study where there was no difference in emergence between the two treatments levels. In the case of the 1 µg a.s./l treatment, from day 56 the concentration was below the peak concentration (0.868 µg a.s./l) occurring on day 16 in the 0.56 µg a.s./l treatment. Statistical analysis of these data also showed that there was no difference between the 0.56 and 1 µg a.s./l treatments and the natural variation in the control. Therefore it is considered that the slight difference in emergence between these two groups from day 70 to 98 is not due to a real difference. On the basis of this information it was concluded that the EAC for Ceratopogonidae should be based on the 0.001 mg a.s./l treatment. It is important to note that the peak measured concentration from this treatment was actually 0.00157 mg a.s./l (Table A7_4_3-1).

The numbers of Chaoboridae were not affected at 0.32 µg a.s./l, at 0.56 to 3.2 µg a.s./l there was a slight decrease in emergence compared to the control with recovery later in the study. Marked effects were seen at 5.6 and 10 µg a.s./l although there was some recovery towards the end of the study. No recovery was observed at concentrations above this.

The number of taxa was also considered for the emergence data. For the concentrations of 0.32 and 1.0 µg a.s./l there was no treatment related effect. At 1.8 µg a.s./l and 3.2 µg a.s./l a treatment related effect could not be excluded for the periods 56 to 77 days and 35 to 42 days respectively. Significant effects on taxonomic richness occurred at the concentrations of 5.6 to 32 µg a.s./l.

The Shannon Weaver diversity Index showed that the test concentrations 0.32 and 1.0 µg a.s./l were similar to the control. At 1.8 µg a.s./l diversity was reduced from about day 56 but there was evidence of recovery towards the end of the study. At 3.2 to 32 µg a.s./l diversity was reduced after the first application and clear recovery was not apparent. Examination of emergence evenness showed there was no clear effect at 0.32 and 1.0 µg a.s./l. At 1.8 to 18 µg a.s./l there was a clear decline in evenness from day 56, probably due to the extremely high proportion of chironomids. At the end of the study a slight recovery of evenness was noted at 1.8 – 3.2 µg a.s./l.

The Stander's index showed there was a good similarity in the controls during the study. It also showed that the controls were comparable with the treatments at the concentrations of 0.32 and 1.0 µg a.s./l. However, at 1.8 to 5.6 µg a.s./l there was a low similarity between the controls and the concentrations of 1.8 to 5.6 µg a.s./l on two occasions (day 42 and 84). At the two highest concentrations there was low similarity for the whole period from day 42 to 84. At the end of the study some recovery of evenness was apparent at all concentrations except the highest two.

The emergence results are summarised in Table A7_4_3-3. On the basis of the information presented it was concluded that the Ecologically Acceptable Concentration (EAC) for emergence was from the 1.0 µg a.s./l treatment (peak measured concentration 1.57 µg a.s./l).

Zooplankton

There was no effect on the total number of zooplankton at 0.32 – 3.2 µg a.s./l. At 5.6 – 32 µg a.s./l higher numbers of zooplankton were recorded between day 8 and 42. A total of 25 emergence species were identified consisting of 4 major taxonomic groups; Rotatoria (13 species), Ostracoda (only identified as Ostracoda), Copepoda (at least 3 species) and Cladocera (9 species).

Rotatoria were not reduced by the treatments. At the higher concentrations (5.6 to 32 µg a.s./l) there was an increase in numbers between day 8 and 42. At 3.2 µg a.s./l there was only a slight increase compared with the control from day 8 – 56. The reason for this effect was probably due to an impact on the copepoda populations at the higher concentrations and hence a reduction in competition.

The Copepoda population decreased after the first application (10 – 32 µg a.s./l) and second application (5.6 µg a.s./l). At 10 µg a.s./l the population was virtually extinct by day 10. At 5.6 µg a.s./l the population was also severely affected although by the end of the study there was a very slight increase in the population. At 3.2 µg a.s./l the

population decreased slowly throughout the course of the study. At the lower concentrations there was little effect on numbers compared to the control. The Naupliae were a major fraction of the Copepoda and the results were the same as described above. The Copepodite also showed similar results to the Copepoda and the Naupliae. There was a clear reduction in numbers at 5.6 – 32 µg a.s./l. At 3.2 µg a.s./l there was again a reduction in numbers throughout the course of the study. However, for the Copepodites there was a slight depression in the population at 1.0 and 1.8 µg a.s./l for 3-6 weeks after the second application, the population then recovered. It should be noted that there was also some variation between the control microcosms.

Ostracoda were present as only a minor fraction of the total zooplankton. At 3.2 to 32 µg a.s./l there was a reduction in numbers. At 3.2 µg a.s./l there was a slight increase in numbers from day 63 and also at 5.6 and 10 µg a.s./l from day 42. However, numbers were still low at the end of the study. Cladocera also occurred at low levels. There was no clear dose related effect on numbers throughout the duration of the study.

The number of species indicated no effects of dosage and there was also no effect on the Shannon-Weaver index of diversity. The Stander's index showed a high degree of similarity within the controls. This was especially the case for the first 8-10 weeks, after this period there was some decrease in similarity. At the concentrations 0.32 and 1.0 µg a.s./l it was considered that there was not an effect on species composition. After day 42 the similarity of the 1.8 and 3.2 µg a.s./l treatments compared with the control decreased. A much greater effect was seen at the higher concentrations.

The results are summarised in Table A7_4_3-4. The EAC for zooplankton was considered to be 1.8 µg a.s./l based on these data.

Macrozoobenthos

A total of 20 species and genera were identified. However, the majority were only present in very low numbers. Due to the high efficiency of the sampling method for emerging organisms and the low numbers of these organisms in the macrozoobenthos samples the results were not discussed in much detail. The results were comparable with those for emerging organisms. Data for the sum of macrozoobenthos showed that there was no effect up to 3.2 µg a.s./l. At 0.56 µg a.s./l there was a high peak on day 22 and 28, a similar but less pronounced effect was seen in one of the controls. At 5.6 to 32 µg a.s./l there was a decrease in numbers. There was some indication of some recovery at 5.6 µg a.s./l from day 56 and towards the end of the study at higher concentrations.

The results are summarised in Table A7_4_3-5 and the EAC for macrozoobenthos was considered to be 3.2 µg a.s./l.

Phytoplankton

The taxonomic groups identified were Cryptophyta, Chlorphyceae, Cyanophyta, Conjugatophyceae, Diatomeae, Xanthophyceae and

Euglenophyta. The latter two groups were only found in low numbers and not in all microcosms and so are not discussed in detail.

The sum of phytoplankton during the pre-treatment period was comparable for the different microcosms. Until day 42 the sum of phytoplankton in all the treated and control microcosms was comparable. At 0.32 and 0.56 µg a.s./l the numbers also remained comparable for the rest of the period. At 1.0 to 32 µg a.s./l the cell numbers were lower from day 42 to 77. This may have been due to higher Rotaria numbers and/or nutrient competition by the periphyton algae. Towards the end of the study period cell numbers in all treatments were close to the control.

The major algae fraction was the Cryptophyta. There was no clear dose related effect of treatment on numbers throughout the course of the study. For the Chlorophyceae there was a major increase in numbers around day 40 followed by a major decrease in numbers in the control towards the end of the study. At 0.32 and 0.56 µg a.s./l the results were comparable with the control. At 1.0 and 1.8 µg a.s./l the increase in numbers was much less than in the control. At the higher concentrations there was no major increase in numbers as seen in the control with numbers remaining low throughout the study. From day 56 the Cyanophyta constituted a major fraction of the microcosms. Numbers increased beyond the control in the treatments 3.2 to 32 µg a.s./l. It was considered that this effect was probably due to the lack of competition of Chlorophyceae.

There were low levels of Conjugatophyceae in the controls. There was an increase in numbers in the treatments towards the later half of the study but there was no clear dose related effect. Levels of Diatomeae were low in controls. Higher densities occurred in the treated microcosms however, this difference cannot be linked to treatment since higher levels occurred in the pre-treatment period in these microcosms.

Since only major taxonomic groups were identified the Shannon Weaver index of diversity, evenness and number of taxa could not be used. The Stander's index indicated a high degree of similarity of all microcosms until day 35. The degree of similarity of the controls and the 0.32 and 0.56 µg a.s./l treatments was high until the end of the study. The similarity of the 1.0 µg a.s./l treatment with the control was high until the end of the study with a slight reduction from day 56. The index at 1.8 and 3.2 µg a.s./l was reduced was distinctly reduced on day 77 and 56 respectively. The Stander's index showed that at 5.6 to 32 µg a.s./l there was little similarity with the control between day 56 and 77. However, after day 84 the similarity of the ponds was again high with the exception of the 32 µg a.s./l treatment. It was considered that the difference in similarity at test concentrations above 1.0 µg a.s./l was probably due to the difference in dominance of Chlorophyceae and Cyanophyta compared with the control ponds.

The results for the phytoplankton are summarised in Table A7_4_3-6. On the basis of these results the regulatory EAC for phytoplankton was considered to be 3.2 µg a.s./l. However, it should be noted that the

Section A7.4.3 **Effects on aquatic organisms, further studies**

Annex Point IIIA XIII.2 Microcosm study

effects on the phytoplankton were indirectly caused by effects on their grazers and not from the direct toxicity of the active substance to the algae.

Macrophytes and periphyton algae

Only one aquatic macrophyte was recorded, this was *Elodea canadensis*. There was no dose related effect on the development of this macrophyte during the study. At the end of the study 75-90% of the sediment was covered with macrophytes in all the microcosms.

The abundance of periphyton algae was visually assessed using a key (0: no periphyton algae; 5 : nearly all walls and water surface covered with periphyton algae). There was no effect on the abundance of periphyton algae up to day 28. Subsequently the numbers increased in all microcosms due to an increase in temperature. There was however no clear relationship of treatment with abundance.

5 CONCLUSION

5.1 Conclusion

In conclusion the overall Ecologically Acceptable Concentration (EAC) obtained in the microcosm study was the 1 µg a.s./l treatment, based on emergence of Ceratopogonidae (an insect group). It is important to note that, since two applications were made, the measured concentration from this treatment was actually 1.57 µg a.s./l. Therefore the overall EAC for this study is 1.57 µg a.s./l. 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	17/11/06

Materials and Methods

[redacted]

Table A7_4_3_a Sampling intervals

Day	Zooplankton[1]	Phytoplankton[2]	Emergence[3]	Benthos[2]
-14	X	-	X	-
-7	X	X	X	-
0	X	X	X	X
2	X	-	-	-
4	X	X	-	-
7	X	X	X	X
14	X	X	X	X
16	X	-	-	-
18	X	X	-	-
22	X	X	X	X
28	X	X	X	X
35	X	X	X	X
42	X	X	X	X
49	-	-	X	-
56	X	X	X	X
63	-	-	X	-
70	-	-	X	-
77	X	X	X	-
84	X	X	X	X
91	-	-	X	-
98	X	X	X	X

X sampling took place
- no sampling occurred
[1] Two mixed samples of 2 individual samples each
[2] One mixed sample of 4 individual samples
[3] One mixed sample of 1 emergence trap

The Applicant states that a total of 13 insect genera were identified. However, the list is of the 4 major taxonomic groups that were identified.

Results and discussion

[redacted]

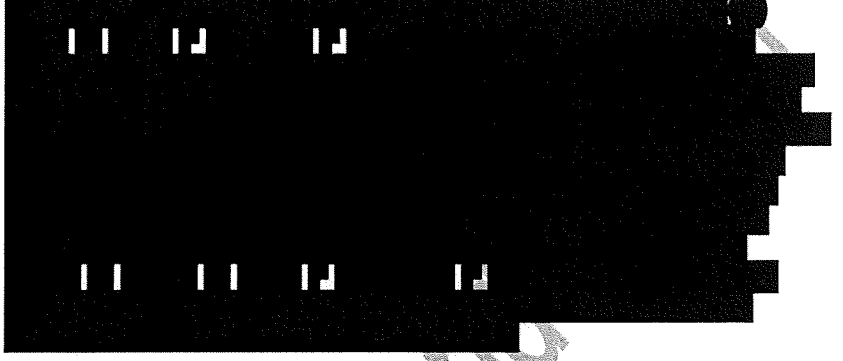


Table A7_4_3_b NOECs

Biological examinations	NOEC (µg/l)
Emergence	[redacted]
Zooplankton	[redacted]
Benthos	[redacted]
Phytoplankton	[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_4_3-1 Results for the peak concentrations of YRC 2894 (µg a.s./l) relative to the initial nominal in the microcosm study on day 16 (two days after the second application)

Nominal conc'n (µg a.s./l)	0.32	0.56	1.0	1.8	3.2	5.6	10	18	32
Measured conc'n (µg a.s./l)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Conc'n = concentration

Table A7_4_3-2 Ceratopogonidae individuals found in the emergence traps per treatment concentration (ppb is equivalent to µg a.s./l) up to 70 days

day	control mean	0.32 ppb	0.56 ppb	1 ppb	1.8 ppb	3.2 ppb	5.6 ppb	10 ppb	18 ppb	32 ppb
0-70	132.98 range (60-242)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table A7_4_3-3 Summary of results for emergence at the different concentrations of YRC 2894

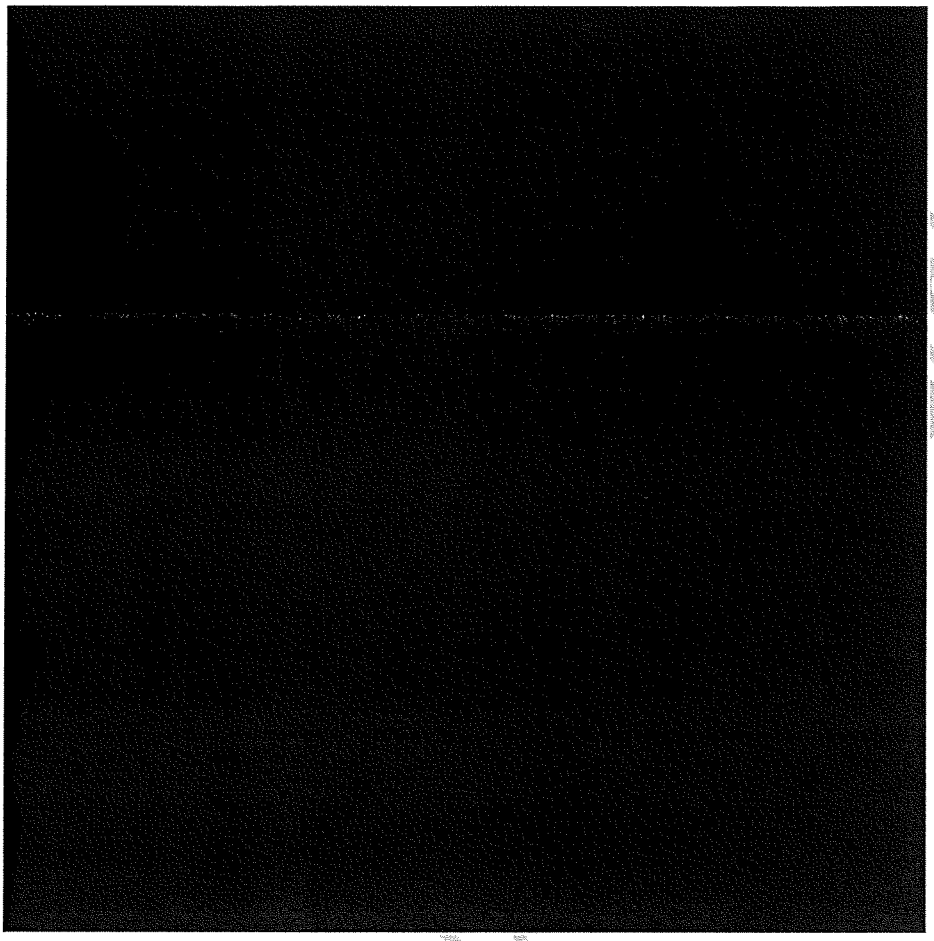


Table A7_4_3-4 Summary of results of zooplankton at the different concentrations of YRC 2894

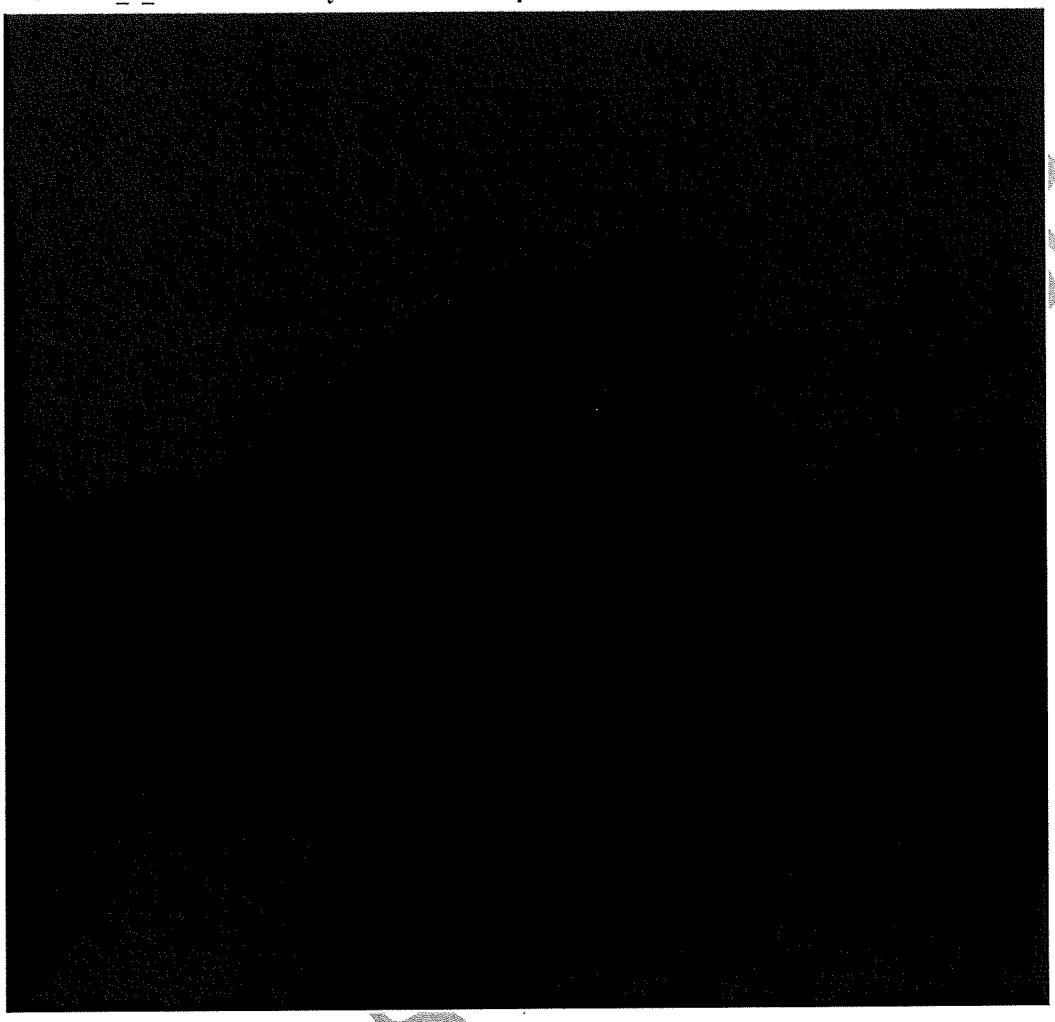


Table A7_4_3-5 Summary of results of macrozoobenthos at the different concentrations of YRC 2894

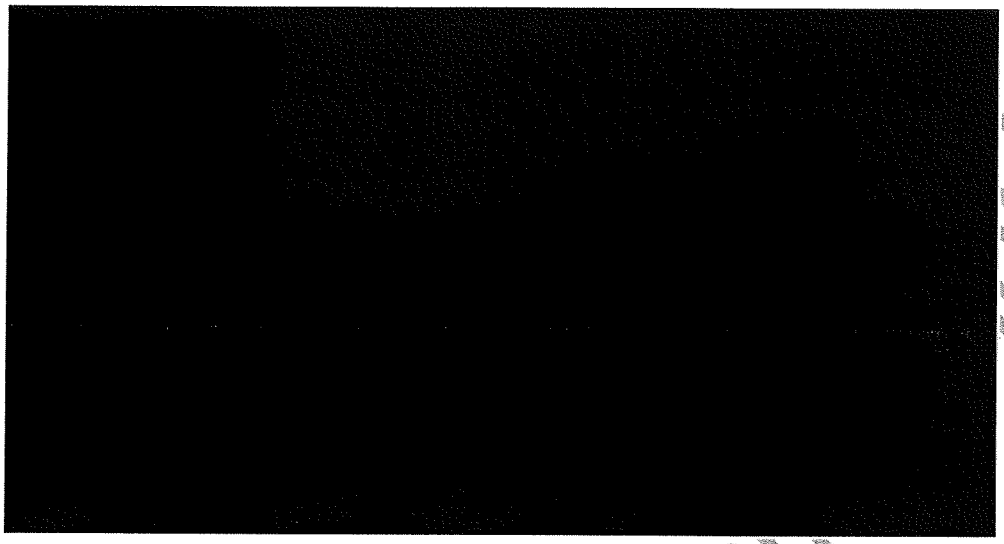
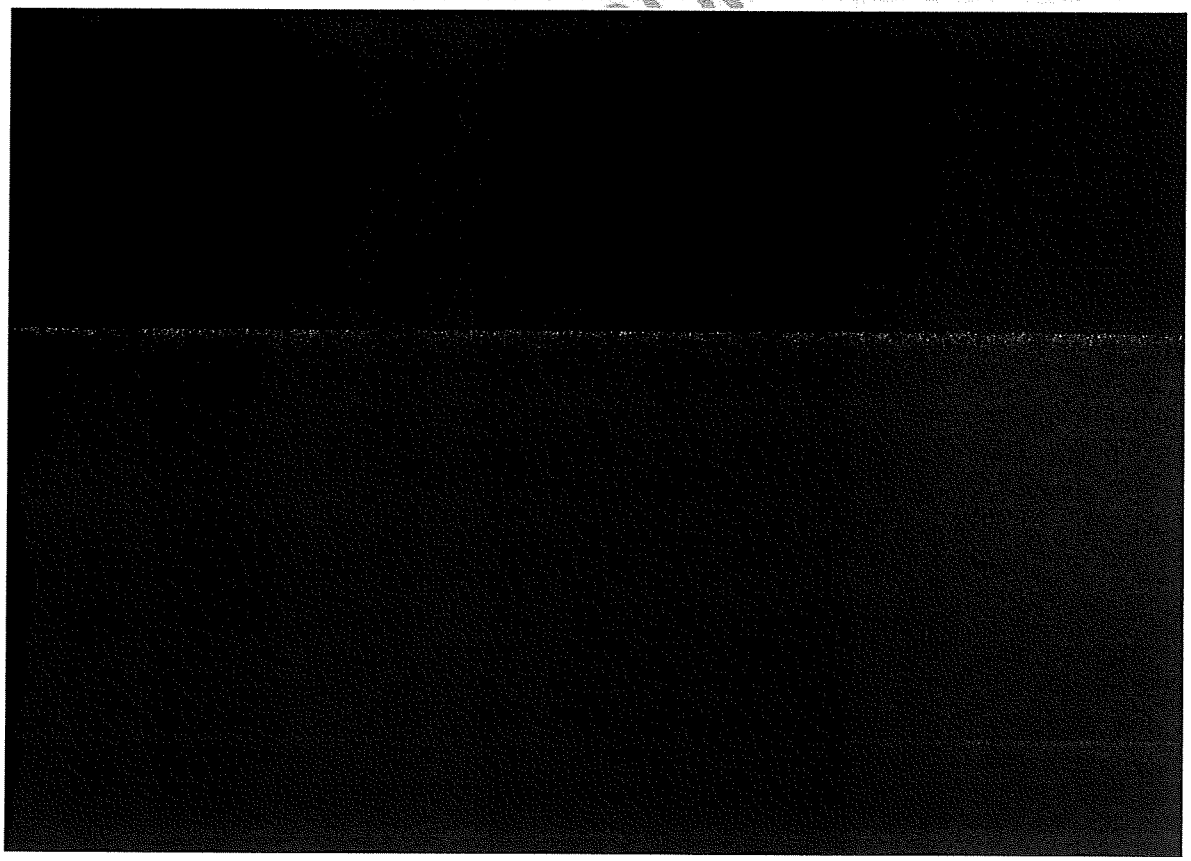


Table A7_4_3-6 Summary of results of phytoplankton at the different concentrations of YRC 2894



Section A7.4.3.1 Annex Point IIIA, XIII.2.1	Effects on Prolonged toxicity to an appropriate species of fish	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [ ] Other justification [...]	
Detailed justification:	The available data concerning acute toxicity and effects on reproduction in fish is sufficient. Additionally, this test 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	08/08/06	
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 A7.4.3.2 Fish Early Life Stage Test

Annex Point IIIA XIII 2.2 *Oncorhynchus mykiss*

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] 1997): YRC 2894 technical- early life stage toxicity to rainbow trout (*Oncorhynchus mykiss*) under flow-through conditions. [redacted] Report No [redacted] 5018, date: 1997-08-05. *PPP-Monograph Chapter: B.9.2 Effects on aquatic organism, B.9.2.2 Chronic toxicity - a) Fish*	
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 210 and US-EPA guideline 72-4	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		A 97-day fish early life stage, flow-through study was undertaken with eggs, larvae and juveniles of rainbow trout (*Oncorhynchus mykiss).* These were exposed to nominal concentrations of 0.122, 0.243, 0.486, 0.972, 1.94 and 3.98 mg/l YRC 2894 (thiacloprid, purity [redacted]%). A solvent control of 1-methyl-2-pyrrolidon was also included. Mean measured concentrations during the test were 0.122, 0.244, 0.483, 0.918, 1.91 and 3.91 mg a.s./l and results were expressed in terms of these. There were four replicates containing 35 embryos in each test group. Once over 95% of the eggs had reached the swim up stage the number of larvae was thinned to 15 per replicate to prevent overcrowding. The physical parameters in the test were as follows: temperature 9.9 °C (range 9.2-11.1), dissolved oxygen 96-98% (range 91-101) and pH 7.3 (range 7.1-7.5).	X
		4 RESULTS	
		Egg viability was assessed 13 days after fertilisation by taking four groups of 50 eggs, mean viability was 80% (range 76-90%). Fry survival was assessed on study day 69 (post hatch day 34) and was comparable with the control up to 0.483 mg a.s./l. At concentrations above this there were significant differences from the control. The results were as follows; 0.918 mg a.s./l (95%), 1.91 mg a.s./l (98%) 3.91 mg a.s./l (97%) compared with the pooled control at 100%. This effect was no longer apparent at the end of the study, due to mortality in the	

controls in the same range. At day 97 fry survival was not significantly different between the treatments and the controls being between 95-100%. There were no significant differences between the treatments and the control. On the basis of these results the NOEC was stated to be 3.91 mg a.s./l.

Egg hatchability was analysed at day 38 and was between 87-97% (after correction for embryo viability; see above). There were no significant differences between any of the treatments and the pooled controls. There was also no effect of any of the treatments on the time to hatch. The NOEC for both these parameters was 3.91 mg a.s./l. Swim up of newly hatched fry occurred on study day 51. There was only a significant difference from the controls at 3.91 mg a.s./l. The NOEC for swim up was therefore considered to be 1.91 mg a.s./l.

There was a significant difference in fry growth (length) on study day 69. Length was significantly reduced ($p = 0.05$) at 0.483, 0.918, 1.91 and 3.91 mg a.s./l. The lengths at 0.483, 0.918 and 1.91 mg a.s./l were 26 mm, and 25 mm at 3.91 mg a.s./l. This was compared with the control at 27 mm. At study date 97 there was a significant effect ($p = 0.05$) on fry growth at 1.91 and 3.91 mg a.s./l. Length was 31 mm in the control compared with 30 and 29 mm at 1.91 and 3.91 mg a.s./l. Fry dry weight was also significantly reduced at day 97 at 0.483, 0.918, 1.91 and 3.91 mg a.s./l being 47, 53, 46 and 43 mg respectively. The control fry weight was 55 mg. The NOEC for fry length at day 69 was 0.244 mg a.s./l. At day 97 the NOEC for fry length was 0.918 mg a.s./l and for fry weight was 0.244 mg a.s./l.

Observations were also made for morphological and behavioural effects. There were no dose related effects except a dark coloration and quiescence at 3.91 mg a.s./l. The NOEC for this parameter was 1.91 mg a.s./l.

A summary of the effect based on egg survival, time of hatch, hatchability, posthatch success, growth and morphological and behavioral effects, the test revealed the results presented in the Table A7_4_3_2-1.

5 CONCLUSION

5.1 Conclusion

The lowest NOECs were 0.24 mg a.s./l for fry length (although no effect was apparent at this dose by day 97) and fry weight at day 97. 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	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	

Table A7_4_3_2-1 Early life-stage toxicity (97 days) of thiacloprid with *Oncorhynchus mykiss* under static conditions

Time to Hatch:	NOEC:	[redacted]	LOEC:	[redacted]
Hatchability (hatching success)	NOEC:	[redacted]	LOEC:	[redacted]
Post-hatch success (fry survival)	NOEC:	[redacted]	LOEC:	[redacted]
Growth (Length & Weight)	NOEC:	[redacted]	LOEC:	[redacted]
Morphological & Behavioral Effects	NOEC:	[redacted]	LOEC:	[redacted]

Section 7.4.3.4 — Effects on reproduction and growth rate with an invertebrate species

Annex Point IIIA XIII 2.4 — Daphnia magna

			Official use only
		1 REFERENCE	
1.1	**Reference**	Heimbach, F. (1996a): Influence of YRC 2894 (techn.) on the reproduction rate of water fleas (*Daphnia magna*). Bayer AG, Report No. HBF/RDM 54, date: 1996-01-05. *PPP-Monograph Chapter: B.9.2 Effects on aquatic organism. B.9.2.2 Chronic toxicity - b) Aquatic invertebrates*	
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 guideline 72-4	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	X
		3 MATERIALS AND METHODS	
		The chronic toxicity of YRC 2894 (thiacloprid, purity [redacted]%) to *Daphnia magna* (first instars < 24 hours) was assessed in a 21-day study conducted under static renewal conditions. There were 10 replicates (1 daphnid/vessel) for each concentration and the control to monitor reproduction and growth. There were also three vessels (5 daphnia/vessel) to monitor survival. The daphnia were transferred to freshly prepared test media three times per week.	X
		The nominal concentrations tested were 0.10, 0.32, 0.56, 1.0, 1.8, 3.2, 5.6 and 10 mg a.s./l. Mean measured concentrations were determined to be 0.11, 0.33, 0.58, 1.05, 1.85, 3.30, 5.80 and 10 mg a.s./l based on sampling on four occasions. The physical-chemical parameters remained within the requirements of the protocols throughout the test period. Results were based on mean measured concentrations.	
		4 RESULTS	

Section 7.4.3.4 — **Effects on reproduction and growth rate with an invertebrate species**

Annex Point IIIA XIII 2.4 — Daphnia magna

No mortalities occurred in the parental daphnia with the exception of one mortality at 0.58 mg a.s./l. There was a significant effect ($p = 0.05$) on the sum of offspring per parent at 5.8 and 10.0 mg a.s./l. The numbers were 74.2% and 36.6% respectively relative to the control. There was also a significant effect on the number of offspring per parent and the reproductive day at 5.8 and 10.0 mg a.s./l. The values relative to the control were 76.6% and 40.7 % respectively. The data showed that there was no significant difference in sex of emerged midges between the control and the treatments. X

There was a significant effect ($p = 0.05$) on body length of parents at all the concentrations from 1.05 to 10.0 mg a.s./l. The lengths for the control and for the treatments 1.05, 1.85, 3.30, 5.80 and 10.0 mg a.s./l were as follows; 4.54 mm,4.33 mm, 4.02 mm, 3.80 mm, 3.60 mm and 3.03 mm. There was also a significant effect on dry weight at 3.3, 5.80 and 10.0 mg a.s./l. The dry weights were 0.45, 0.38 and 0.29 mg respectively, compared with the control at 0.65 mg. The NOECs for the parameters measured in the test are summarised in Table 9.11.

The lowest NOEC is 0.58 mg a.s./l based on the body length of parent animals.

A summary of results obtained from this study is presented Table A7_4_3_4-1.

5 CONCLUSION

5.1 Conclusion — The lowest NOECs was 0.58 mg/l for body length of parent animals. 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	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

Table A7_4_3_4-1 Summary of NOECs for Daphnia magna in a 21-day static renewal study

Test organism	*Daphnia magna*			
Findings/ Results Parameters	Sum of offspring/ parent	number of offspring/ parent and reproduction-day	body length of parent animals	dry weight of parent animals
Highest tested conc. without toxic effect (NOEC) mg a.s./l	[redacted]	[redacted]	[redacted]	[redacted]

Section A7.4.3.5.1 Effects on sediment dwelling organisms (4)

Annex Point IIIA, XIII.3.4 **Leachate water**

Chironomus riparius (midge larvae)

			Official use only
		1 REFERENCE	
1.1	**Reference**	Heimbach, F. (1997c [*Addendum I: 1997*]): Acute toxicity of leachate water samples of lysimeter studies on YRC 2894 to larvae of chironomus riparius. Bayer AG, Report No. HBF/CH 15, date: 1997-02-26. *Addendum I to PPP-Monograph; Chapter: B.9.2 Effects on aquatic organisms. B.9.2.1 Groundwater [Evaluation table point 2.5]- Effects on sediment dwelling organisms (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 was undertaken with *Chironomus riparius* (first instar larvae) using leachate water samples of thiacloprid treated lysimeters and a leachate water control and a control (Table A7_4_3_5_1-1). These concentrations are comparable with those obtained in the lysimeter study of Brumhard in 1998 (*cf.* Study Summary A7.2.3.2, 2nd) for Year 2 that are summarised below in Table A7_4_3_5_1-2. The slight differences in actual values can be accounted for by differences arising between annual averages from individual samples and those from mixed samples. Table A7_4_3_5_1-2 therefore indicates the levels of Z5 and other thiacloprid metabolites tested in the study. Each test solution was tested undiluted and in two dilution steps (1:1 and 1:2 i.e. 37.5 ml sample material and 37.5 ml test water and 25 ml sample material and 50 ml test water respectively). A 25 ml sample was used at each test concentration and the animals added immediately after. There were 10 animals in each replicate and three replicates per test concentration and in the control. The 100 ml beakers were kept at 20 ± 1 °C and a 16:8 light-dark cycle at 1100 lux.	X

Section A7.4.3.5.1 Effects on sediment dwelling organisms (4)

Annex Point IIIA, XIII.3.4 **Leachate water**

Chironomus riparius (midge larvae)

4 RESULTS

The control mortalities were below 10% at both 24 and 48 hours. No mortality higher than 3.3% and no signs of intoxication occurred in any of the treatments i.e. in the undiluted and diluted leachate water samples or leachate control. It was considered that the leachate water did not affect the larvae.

5 CONCLUSION

5.1 Conclusion

Leachate water was obtained from the lysimter study by Brumhard (1998c). Leachate did not affect the larvae of the sediment water organism tested.

The study was well performed and reported, according to the test guideline for acute Daphnia toxicity, but using *Chironomus riparius*.

[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	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	

Table A7_4_3_5_1-1 **Details of lysimeter leachates (after application of thiacloprid) tested in the *C. riparius* study**

OE-label	Lysimeter	Other information	Residue-equivalent-concentration
sample 1	21	Mixed sample collected from May 1995 to May 1996	[redacted]
sample 2	22	Mixed sample collected from May 1995 to May 1996	[redacted]
sample 3	21	Individual sample collected April 26, 1996	[redacted]
sample 4	Leachate water control	sample of an untreated lysimeter collected January 24, 1997	---

Table A7_4_3_5_1-2 **Identification of radioactivity from the leachate (all average concentration 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). Information taken from Burmhard**

	Concentrations in leachate							
	Total	Thia-cloprid	M02	M30	M34	Z5*	M32	Unidentified
Year 2[1]								
Peak	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Annual mean	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

*values amended from the draft assessment report to account for molecular weight of 275g/mole as Z5 is now identified.

Year 2[1] = May 1995 to May 1996.

Section A7.4.3.5.1 Effects on sediment dwelling organisms (1)

Annex Point IIIA, XIII.3.4 *Chironomus riparius* (midge larvae, arthropod)

			Official use only
		1 REFERENCE	
1.1	**Reference**	Heimbach, F. (1996b): Influence of YRC 2894 (techn.) on development and emergence of larvae of *Chironomus riparius* in a water-sediment system. Bayer AG, Report No. HBF/Ch 09, date: 1996-04-03. *PPP-Monograph Chapter: B.9.2 Effect on aquatic organisms, B.9.2.2 Chronic effects - c) Effects on sediment dwelling organisms (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 method for plant protection products.	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		A 28 day static chronic study was undertaken with *Chironomus riparius* using thiacloprid, purity: [redacted]%. There were 25 larvae (L1-larval stage) for each test concentration. The test container was filled with a 2 cm high layer of an artificial sediment and 20 cm reconstituted overlying water = 2.65 l test water/ special nutrient solution. The nominal initial concentrations in the water fraction were 0.00032, 0.00056, 0.001, 0.0018, 0.0032, 0.0056 and 0.010 mg a.s./l. The active substance was introduced beneath the water surface and gently mixed. The test sediment contained 69% sand, 10% peat, 20% kaolin and 1% calcium carbonate. During the study, number, sex and time of emergence of emerged midges were determined daily. The emergence rate of male and female midges was pooled for the statistical analysis, as this effect was not treatment related.	X
		4 RESULTS	
		The analytical findings of the 1h sampling of the initial nominal test concentrations 0.00032, 0.0018 and 0.010 mg a.s./l were 83 to 113% of nominal (on average 98.3%), therefore results were based on nominal initial concentrations. The concentration of active substance in the water phase declined over the course of the study. On day 7 on average 64.5% and on day 28 on average 15.7% of the nominal initial values	X

Section A7.4.3.5.1 **Effects on sediment dwelling organisms (1)**

Annex Point IIIA, XIII.3.4 *Chironomus riparius* (midge larvae, arthropod)

were found. The average amount of active substance in the pore water also decreased over the course of the study. It was 3.4% of the nominal applied amount at day 0, 1.3% on day 7 and 0.1% on day 28. Recorded temperatures, pH values and oxygen levels were similar between the different the treatments and the control.

At test concentrations higher than 0.0018 mg a.s./l no adult midges emerged. The EC_{50} for emergence was determined to be 0.00218 mg a.s./l. At 0.0018 mg a.s./l the day of first emergence was delayed until day 16 compared with the control (and lower concentrations) at 14 days. At concentrations with successful emergence (0.00032 to 0.0018 mg a.s./l) a significant dose-response relationship can be excluded. The EC_{50} for development rate was determined to be >0.0018 mg a.s./l. A statistical calculation of this parameter was not possible due to a steep concentration response. A NOEC for this study was not presented by the study author, however based on a delay in emergence and a slight reduction in the numbers emerged at 0.0018 mg a.s./l the NOEC was considered to be 0.001 mg a.s./l.

5 CONCLUSION

5.1 Conclusion [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	20/04/07
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 A7.4.3.5.1 Effects on sediment dwelling organisms (2)

Annex Point IIIA, XIII.3.4 **Metabolite M02**

Chironomus riparius (midge larvae)

			Official use only
		1 REFERENCE	
1.1	**Reference**	Heimbach, F. (1997b *[Monograph: 1997a]*): Influence o[redacted]n development and emergence of larvae of *Chironomus riparius* in a water-sediment system. Bayer AG, Report No. HBF/Ch 12, date: 1997-02-26. *PPP-Monograph Chapter: B.9.2 Effect on aquatic organisms. B.9.2.2 Chronic toxicity - c) Effects on sediment dwelling organism - Product (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; German BBA method for plant protection products	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		A 28-day static study was undertaken with *Chironomus riparius* using metabolite M02 ([redacted]), purity: [redacted]% at a nominal concentration of 0.1 mg metabolite/l. There were 25 larvae (L1-larval stage) at the test concentration and in the control and solvent control. The test container contained a 2 cm high layer of an artificial sediment and 20 cm reconstituted overlying water = 2.65 l test water/ special nutrient solution. The metabolite was introduced beneath the water surface and gently mixed. The test sediment contained 69% sand, 10% peat, 20% kaolin and 1% calcium carbonate. The concentration of M02 was analysed three times on days 0, 8 and 28.	X
		4 RESULTS	
		The concentrations in the overlying water declined throughout the course of the study. At 1 hour they were 120% of nominal, 78.4% on day 8 and 49.4% on day 28. A slight increase in the level in the pore water occurred. On day 0 the concentration in the pore water was below the detection limit of 0.01 mg metabolite/l. At day 8 the pore water concentration was increased to 0.68% of the applied nominal and remained at this level until day 28 (0.71% of nominal).	

Section A7.4.3.5.1 **Effects on sediment dwelling organisms (2)**

Annex Point IIIA, XIII.3.4 **Metabolite M02**

Chironomus riparius (midge larvae)

The % emergence of midges in the control fulfilled the guideline requirements: 91%. In this study no statistically significant difference in numbers of emerged midges was observed. The number of emerged midges and the development rate were not influenced at the test concentration of 0.1 mg metabolite/l. Also the day of first emergence was not postponed. There was also no influence on the numbers of emerged midges per sex. It was therefore concluded that the NOEC was 0.1 mg/l M02, the highest concentration tested. The EC_{50} of metabolite M02 is greater than 0.1 mg/l.

5 CONCLUSION

5.1 Conclusion

Only one test concentration tested (0.1 mg/l) with metabolite M02, as no M02 was found in leachate in the lysimeter study by Brunmhard (1998c). No effects were observed at this concentration level..

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	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	

Section A7.4.3.5.1 Effects on sediment dwelling organisms (3)

Annex Point IIIA, XIII.3.4 **Metabolite M30**

Chironomus riparius (midge larvae)

			Official use only
		1 REFERENCE	
1.1	**0Reference**	Dorgerloh, M. and Sommer, H. (2002): Influence of thiacloprid-sulfonic acid Na-salt on development and emergence of larvae of *Chironomus riparius* in a water-sediment system. Bayer AG, Report No. DOM 22022, date: 2002-03-20. *Addendum I to PPP-Monograph; Chapter: B.9.4 Metabolites M02 (YRC 2894-amide; KKO 2254) and M30 (YRC 2894 sulfonic acid, sodium salt; WAK 6999). B.9.4.1 Effects on sediment dwelling organisms (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 method for plant protection products and OECD guideline 219.	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		A 28 day static study was undertaken with *Chironomus riparius* using M30, purity [redacted]%. There were 20 larvae (L1-larval stage) in each test concentration and three replicates. The test container was filled with a 1.5 cm layer of sediment and 0.38 l of water/nutrient solution. The nominal initial concentrations in the water were 10, 18, 32, 56 and 100 mg/l. The metabolite was introduced beneath the water surface and gently mixed. The test sediment contained 74% sand, 5% peat, 20% kaolin and 1% calcium carbonate.	X
		Analytical sampling was undertaken on three occasions (1 hour, 7 and 28 days after application). The analytical results for the test concentrations of 10, 32 and 100 mg metabolite/l were 86.3 to 90.6% at 1 hour after application. The concentration of the active substance in the overlying water declined negligibly during the course of the study. On day 7 the test concentrations were 75.6 – 83% of nominals and on day 28 were 73.9 – 74.8%. Concentrations in pore water were low throughout the study being 1% on day 0, 4.2% on day 7 and 5.3% on day 28. Recorded temperatures, pH values and oxygen levels were similar between the different the treatments and the control.	X
		During the study, number, sex and time of emergence of emerged	

Section A7.4.3.5.1 **Effects on sediment dwelling organisms (3)**

Annex Point IIIA, XIII.3.4 **Metabolite M30**

Chironomus riparius (midge larvae)

midges were determined daily.

4 RESULTS

The emergence rate of male and female midges was pooled for the statistical analysis, as this effect was not treatment related. The percentage emergence of midges in the controls fulfilled the guideline requirements and for the concentrations of 10 to 100 mg/l metabolite emergence was between 82 to 95%. The start of emergence was on day 14 and 15 for all the test concentrations and the control. Mean development time was less than 20 days and there was no difference between the controls and treatments. Only for two vessels at 56 mg/l was there a statistically significant difference in the number of emerged midges per sex. No statistically significant difference was found for the other vessels at this test concentration or at lower and higher concentrations. Therefore it was considered that this effect was not treatment related. X

Statistical analysis also showed that the number of emerged midges (sum of male and female) did not differ between the control and the test concentrations. Similarly the development rate did not differ between the control and test concentrations.

The results, based on nominal concentrations, are shown in Table A7_4_3_5_1-1.

5 CONCLUSION

5.1 Conclusion

The metabolite M30 is less sensitive than thiacloprid (28d-EC_{50} > 100 mg/l). 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	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	

Table A7_4_3_5_1-1 NOEC and EC15 for emergence ratio and development rate for M30

	NOEC *) (mg pure metabolite/l)	EC_{15} (mg pure metabolite/l)
Emergence ratio (polled sex)	[redacted]	[redacted]
Development rate (polled sex)	[redacted]	[redacted]

*) Dunnett-test, p = 0.05

Section A7.4.3.5.2 Aquatic plant toxicity

Annex Point IIIA, XIII.3.4 *Lemna gibba*

			Official use only
		1 REFERENCE	
1.1	**Reference**	Dorgerloh, M. (1996): YRC 2894 - toxicity (15 days) to *Lemna gibba* G3. Bayer AG, Report No. DOM 95085, date: 1996-03-01. *PPP-Monograph Chapter: B.9.2 Effects on aquatic organisms. B.9.2.1 Acute toxicity (Table 9.7_Study 7)*	
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 123-2	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		The acute toxicity of the thiacloprid (purity [redacted] %) to the aquatic plant *Lemna gibba* was studied for 15 days under static conditions to the mean measured concentrations of 2.98; 6.05; 12.3; 25.7; 46.8 and 95.4 mg as/L. Growth was determined by counting of fronds on days 2, 5, 7, 9, 12 and 15.	X
		4 RESULTS	
		Based on measured concentration for thiacloprid the 15d-EC_{50} was reported to be above to the highest tested concentration 95.4 mg/l. There was 32% growth inhibition (based on frond number) at this test level. An effective EC_{50} of 142 mg a.s./l was proposed as a 'rough estimate' by the study author, although this is outside the range of test concentrations. The NOEC was 46.8 mg test substance/L. The recovery rates found in the analytics were between 96.7-106.2 %.	X
		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 A7.5 Annex Point IIIA12.3	Use of terrestrial eco-toxicity test data from products (e.g. SC 480) in the scope of the biocidal active dossier	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] Limited exposure [...]	Technically not feasible [ ] Scientifically unjustified [ ] Other justification [X]	
Detailed justification:	Because the data on terrestrial toxicity of thiacloprid in the active dossier submitted under the Council Directive 98/8/EC are derived from the data submitted under Council Directive 91/414/EEC, some of the data for thiacloprid are related to a SC 480 plant protection product (SC 480 = suspension concentrate containing approx. 48 % active). In the guidance document on "Terrestrial Eco-toxicology Under Council Directive 91/414/EEC" from 17th of October 2002 (SANCO/10329/2002 rev 2 final) it is stated in chapter 2.4 that: "certain study types may be conducted with a formulated product instead of the active substance. This may be applicable to, for example, non-target arthropod studies, the earthworm reproduction test and the soil micro-flora". Studies on earthworm reproduction and the field test are submitted applying the active by spray application of the SC 480 formulation. In addition with regard to the composition of the SC 480 (for details see confidential part of the dossier) a significant influence of the formulation components on the terrestrial toxicity of thiacloprid is not expected. Taking into account the above mentioned arguments it is justified to use data from a SC 480 product as a surrogate for data on the pure 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	08/08/06	
Evaluation of applicant's justification	[redacted]	

Section A7.5 Annex Point IIIA12.3	Use of terrestrial eco-toxicity test data from products (e.g. SC 480) in the scope of the biocidal active dossier
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 A7.5.1.1 Inhibition to microbial activity (terrestrial) (2)

Annex Point IIIA, XIII 3.3

			Official use only
		1 REFERENCE	
1.1	**Reference**	Anderson, J.P.E. (1995d): Influence of YRC 2894 on microbial mineralization of nitrogen in soils. Bayer AG, Report No. AJO/135895, date: 1995-09-14, *revised 1999-02-10.* *PPP-Monograph Chapter: B.9.8 Effects on soil non-target micro-organisms, B.9.8.1 Toxicity (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; German BBA method Part VI 1-1 and ISO/DIS 1036-6	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		In a study on the influence of technical YRC 2894 (thiacloprid, purity [redacted]%), 2 soils with active microbial biomass (a silty sand and a silt) were exposed for 28 days to concentrations of 0.26 and 2.57 mg a.s./kg dry weight soil. These application rates were equivalent to 0.188 and 1.875 kg a.s./ha (= 1 x and 10 x field rate). The soils were amended with lucerne meal (5000 mg/kg dw soil). Ammonium, nitrite, and nitrate+nitrite concentrations were measured.	X
		4 RESULTS	
		YRC 2894 had no influence on the turnover of nitrogen. During the 28-day experiments, thiacloprid had no influence on soil respiration after addition of lucerne meal to a silty sand or silt soil (Table A7_5_1_1-1).	X
		5 CONCLUSION	
5.1	**Conclusion**	Up to 1.875 kg ai/ha should have no negative influence on the turnover of nitrogen in soils. [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	10/11/06
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	

Table A7_5_1_1-1 Effects of thiacloprid on non-target soil micro-organisms

Test object	Soil Micro-organisms N-Cycle (silty sand soil)	
Exposure	28 days	
mg/kg dry weight soil	0.26	2.57
kg/ha (equivalent)	0.188	1.875
Final Result	[redacted]	[redacted]

Section A7.5.1.2
Annex Point IIIA XIII 3.2

Acute toxicity test to earthworms or other soil non-target organisms (1)

Eisenia fetida Andrei (earthworm)

Official use only

1 REFERENCE

1.1	**Reference**	Heimbach, F. (1994): Toxicity of YRC 2894 (techn.) to earthworms (*Eisenia fetida*). Bayer AG, Report No. HBF/Rg 193, date: 1994-11-28. *PPP-Monograph Chapter: B.9.6 Effects on earthworms. B.9.6.1 Toxicity - active substance*	
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 207
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

In an acute toxicity study on technical thiacloprid (purity, [redacted] %), earthworms *Eisenia fetida andrei* (greater than 2 months old, with a mean body weight of 0.36 g) were exposed for 14 days in an artificial soil to nominal concentrations of 1.0, 3.2, 10, 18, 32, 56, 100, 178, 316 and 1000 mg a.s./kg dry weight substrate. There was also an untreated control. Mortality and weight alterations were recorded. Measured water content of the test soil was 25% at the start and 33% at the end of the exposure period. X

4 RESULTS

The 3% mortality at 32 mg a.s./kg soil was below 10% (which was regarded as the limit for natural mortality) and was not considered to be significant. The LC_{50} was 105 (95% C.L. 90 - 122) mg a.s./kg soil. The NOEC was 1.0 mg a.s./kg soil, based on statistically significant effect on weight change at 3.2 mg a.s./kg soil.

Data recorded at each tested concentration are listed in Table A7_5_1_2-1.

Section A7.5.1.2
Annex Point IIIA XIII 3.2

Acute toxicity test to earthworms or other soil non-target organisms (1)

Eisenia fetida Andrei (earthworm)

5 CONCLUSION

5.1	**Conclusion**	[redacted] The concentrations studied are nominal values, since analytical measurements of the substrate are not specified in the test guideline. [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	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	

Table A7_5_1_2-1 **Results of an acute toxicity study on earthworms for technical YRC 2894 (thiacloprid)**

Concentration (mg a.s./ kg dry weight of soil)	Mean mortality	Mean weight alteration of the survivors after 14 days exposure (%)
Control	[redacted]	[redacted]
1.0	[redacted]	[redacted]
3.2	[redacted]	[redacted]
10	[redacted]	[redacted]
18	[redacted]	[redacted]
32	[redacted]	[redacted]
56	[redacted]	[redacted]
100	[redacted]	[redacted]
178	[redacted]	[redacted]
316	[redacted]	[redacted]
1000	[redacted]	[redacted]

* weights of control and the test concentration do differ significantly (P=0.05)

Section A7.5.1.2
Annex Point IIIA XIII 3.2

Acute toxicity test to earthworms or other soil non-target organisms (2)

Eisenia fetida Andrei (earthworm)

			Official use only
		1 REFERENCE	
1.1	**Reference**	Heimbach, F. (1995c): Toxicity of YRC 2894 SC 480 to earthworms (*Eisenia fetida*). Bayer AG, Report No.: HBF/Rg 214, date: 1995-07-04. *PPP-Monograph Chapter: B.9.6 Effects on earthworms. B.9.6.1 Toxicity – plant protection product (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 207	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		In an acute toxicity study on 'YRC 2894 SC 480' (purity: [redacted] g thiacloprid /L), 40 earthworms *Eisenia fetida andrei* (>2 months old, mean body weight of 0.41 g) per test concentration (4 replicates with 10 earthworms each) were exposed for 14 days in artificial soil containing nominal concentrations of 0.32, 1.0, 3.2, 10, 18, 32, 56, 100, 178 and 316 mg a.s./kg dry weight substrate. There was also an untreated control. Mortality and weight alterations were recorded. Measured water content of the test soil was 25% at the start and 34% at the end of the exposure period.	X
		4 RESULTS	
		Results are presented in Table A7_5_1_2-1. The LC_{50} was 51 (95% C.L. 46 - 56) mg a.s./kg soil. The NOEC was 0.32 mg a.s./kg soil, based on statistically significant effect on weight change at 1.0 mg a.s./kg soil.	

Section A7.5.1.2
Annex Point IIIA XIII 3.2

Acute toxicity test to earthworms or other soil non-target organisms (2)

Eisenia fetida Andrei (earthworm)

5 CONCLUSION

5.1	**Conclusion**	The test substance is a thiacloprid-containing plant protection product. [redacted] The concentrations studied are nominal values, since analytical measurements of the substrate are not specified in the test guideline.	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	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	

Table A7_5_1_2-1 Results of an acute toxicity study on earthworms for 'YRC 2894 SC 480'

Concentration (mg a.s./ kg dry weight of soil)	Mean mortality	Mean weight alteration of the survivors after 14 days exposure (%)
Control	[redacted]	[redacted]
0.32	[redacted]	[redacted]
1.0	[redacted]	[redacted]
3.2	[redacted]	[redacted]
10	[redacted]	[redacted]
18	[redacted]	[redacted]
32	[redacted]	[redacted]
56	[redacted]	[redacted]
100	[redacted]	
178	[redacted]	
316	[redacted]	

* weights of control and the test concentration do differ significantly (P=0.05)

Section A7.5.1.2
Annex Point IIIA XIII 3.2

Acute toxicity test to earthworms or other soil non-target organisms (3)

Metabolite M02

Eisenia fetida (earthworm)

			Official use only
		1 REFERENCE	
1.1	**Reference**	Heimbach, F. (1998): Acute toxicity of KKO 2254 (YRC 2894-Metabolite) to earthworms (Eisenia fetida). Bayer AG, Report No. HBF/RG 276, date: 1998-07-15. *Addendum I to PPP-Monograph; Chapter: B.9.4. Metabolites M02 (YRC 2894-amide; KKO 2254) and M30 (YRC 2894 sulfonic acid, sodium salt; WAK 6999). B.9.4.2 Effects on earthworms -M02.*	
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 207	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
		A 14-day acute toxicity test was undertaken with M02, purity: [redacted] %. Adult *Eisenia fetida* (4 x 10 animals per concentration) were exposed in an artificial soil (10% peat) for 14 days to the concentrations of 1000 mg test substance / kg dry weight soil (nominal concentrations). One control and one reference substance where also run in parallel. Chloroacetate was used as the reference substance.	X
		4 RESULTS	
		Mortality in the control was <10%. The LC_{50} was within the concentration range normally determined in international ring studies. Related to weight alterations and symptoms, the no-observed-effect-concentration (NOEC) was <1000 mg test substance/kg dry weight soil, the lowest-observed-effect-concentration (LOEC) was 1000 mg test substance/kg dry weight soil. Results are shown in Table A7_5_1_2-1.	

Section A7.5.1.2
Annex Point IIIA XIII 3.2

Acute toxicity test to earthworms or other soil non-target organisms (3)

Metabolite M02

Eisenia fetida (earthworm)

5 CONCLUSION

5.1	**Conclusion**	[redacted] The concentrations studied are nominal values, since analytical measurements of the substrate are not specified in the test guideline. [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	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	

Table A7_5_1_2-1 Toxicity of M02 to earthworms after 14 days

Test substance	M02
Test object	*Eisenia fetida*
Exposure	14 d
LC_{50} (mg/kg dry weight soil)	[redacted]

Section A7.5.1.2
Annex Point IIIA XIII 3.2

Acute toxicity test to earthworms or other soil non-target organisms (4)

Metabolite M30

Eisenia fetida (earthworm)

Official use only

1 REFERENCE

1.1	**Reference**	Lechelt-Kunze, C. (2002): Acute toxicity of thiacloprid-sulfonic acid Na-salt to earthworms (*Eisenia fetida*). Bayer AG, Report No. LKC/Rg 397/02, date: 2002-02-27. *Addendum I to PPP-Monograph; Chapter: B.9.4. Metabolites M02 (YRC 2894-amide; KKO 2254) and M30 (YRC 2894 sulfonic acid, sodium salt; WAK 6999). B.9.4.2 Effects on earthworms - M30.*
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 207
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

A 14 day acute toxicity test was undertaken with M30, purity: [redacted] %. Adult *Eisenia fetida* (4 x 10 animals per concentration) were exposed in an artificial soil (10% peat) for 14 days to the concentrations of 10, 32, 100, 316 and 1000 mg test substance / kg dry weight soil (nominal concentrations). One control and one reference substance where also run in parallel. Chloroacetate was used as the reference substance. X

4 RESULTS

Mortality in the control was <10%. The LC_{50} was within the concentration range normally determined in international ring studies. Related to weight alterations and symptoms, the no-observed-effect-concentration (NOEC) was 32 mg test substance/kg dry weight soil, the lowest-observed-effect-concentration (LOEC) was 100 mg test substance/kg dry weight soil.

Results are shown in Table A7_5_1_2-1.

Section A7.5.1.2
Annex Point IIIA XIII 3.2

Acute toxicity test to earthworms or other soil non-target organisms (4)

Metabolite M30

Eisenia fetida (earthworm)

5 CONCLUSION

5.1	**Conclusion**	[redacted]. The concentrations studied are nominal values, since analytical measurements of the substrate are not specified in the test guideline. [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	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	

Table A7_5_1_2-1 Toxicity of M30 to earthworms after 14 days

Test substance	M30
Test object	*Eisenia fetida*
Exposure	14 d
LC_{50} (mg/kg dry weight soil)	[redacted]

Section A7.5.1.3 Acute toxicity to terrestrial plants (1)

Annex Point IIIA, XIII 3.4 ***Brassica napuss, Avena sativa, Glycine max***

			Official use only
		1 REFERENCE	
1.1	**Reference**	Großmann, A. and Meinerling M. (2005): Effects of thiacloprid on terrestrial (non-target) plants: Seedling Emergence and Seedling Growth Test (Dose Response Test). Report No. 23251084. Sponsored by LANXESS Deutschland GmbH. Test facility: IBACON GmbH, date: 2005-07-20. *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; Based on OECD guideline 208	
2.2	**GLP**	[redacted]	X
2.3	**Deviations**	[redacted]	
		3 METHOD	
3.1	**Test material**	Thiacloprid	
3.1.1	Lot/Batch number	Batch number [redacted]	
3.1.2	Specification	As given in section 2 of dossier	
3.1.3	Purity	Purity [redacted] %	
3.1.4	Composition of Product	-	
3.1.5	Further relevant properties	Water solubility of thiacloprid: about 0.185 g/l at 20°C (Krohn, 1996)	
3.1.6	Method of analysis	-	
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Not applicable since water solubility of thiacloprid is about 0.185 g/l	
3.3	**Reference substance**	No	
3.3.1	Method of analysis for reference substance		
3.4	**Testing procedure**		

Section A7.5.1.3 Acute toxicity to terrestrial plants (1)

Annex Point IIIA, XIII 3.4 ***Brassica napuss, Avena sativa, Glycine max***

3.4.1	Dilution water	Not applicable, no dilution with water	
3.4.2	Test plants	*Brassica napa, Glycine max, Avena sativa.* See Table A7_5_1_3-3 for details	X
3.4.3	Test system	See Table A7_5_1_3-4; After application of the test substance into the soil, pots were filled with the soil and sown into the contaminated soil	
3.4.4	Test conditions	See Table A7_5_1_3-5	
3.4.5	Test duration	Exposure time: 21 days after application	
3.4.6	Test parameter	Fresh weight, germination, mortality, visual phytotoxicity (e.g. chlorosis, necrosis, abnormal growth). See Tables A7_5_1_3-4 and A7_5_1_3-5 for details	
3.4.7	Sampling	Visual phytotoxicity ratings: Days 7, 14 and 21; Growth stages (BBCH): Day 21; Fresh weight: Day 21; Number of seedlings (germination): Day 7, 14 and 21; Mortality: Number of living and dead plants was recorded on day 21; All parameters were recorded at the end of the test; additionally, germination and phytotoxicity were recorded after 7 and 14 days. See also Tables A7_5_1_3-4 and A7_5_1_3-5 for details.	X
3.4.8	Method of analysis of the plant material	Not applicable	
3.4.9	Quality control	Yes (Test was performed according to GLP by certified laboratory)	
3.4.10	Statistics	Fresh weight data were tested for normal distribution and homogeneity of variance using Kolmogoroff-Smirnov-Tes and the Cochran-Test. Dunnett Test was used for comparing treatment groups and control. In order to determine the EC_{50} values, a regression analysis was performed (probit-analysis). For the mortality and germination data Fischer's Exact-Test was used. The computer programs used to perform the statistical analyses were ToxRat®, SPiRiT Solutions (2005), Version 2.09. The significance level for all test was 0.05. The decision on weight (one-side, two-side) was made dependent on the data.	

4 RESULTS

4.1 Results test substance

4.1.1	Applied initial concentration	The dosages of the test substance were: 4.1, 10.2, 25.6, 32.6, 45.7, 64.0, 89.6, 125.4, 160.0, 400.0, 1000.0 mg/kg soil dw The concentrations to be tested were derived according to the range finding test. *Brassica napus:* 4.1, 10.2, 25.6, 64.0, 160 mg/kg soil dw	

Section A7.5.1.3 Acute toxicity to terrestrial plants (1)

Annex Point IIIA, XIII 3.4 ***Brassica napuss, Avena sativa, Glycine max***

		Avena sativa: 32.6 to 125.4 mg/kg soil dw *Glycine Max:* 32.6, 45.7, 64.0, 89.6, 125.4 mg/kg soil dw	X
4.1.2	Phytotoxicity rating	See Table A7_5_1_3-6b Phytotoxicity effect, observed on all plant species, were chlorosis, necrosis and growth reduction. Growth stages were reduced from 64 mg test substance/kg soil.	
4.1.3	Plant height	Not described	
4.1.4	Plant dry weights	For fresh weights see Table A7_5_1_3-6a. The most sensitive species in fresh weight was *Brassica napus* (EC50: 27.67 mg a.i./kg soil) followed by *Avena sativa* and *Glycine max* with EC50 values of 51.30 and 83.34 mg a.i./kg soil.	
4.1.5	Root dry weights	Not described	
4.1.6	Root length	Not described	
4.1.7	Number of dead plants	See Table A7_5_1_3-6a Most sensitive species for the parameter mortality was *Brassica napus* which showed mortality from 64 mg a.i./kg soil and above (2.7 % and 5.4 %). For the other species no mortality was observed	
4.1.8	Effect data	See Table A7_5_1_3-7a (effect data based on results of the fresh weight)	
4.1.9	Concentration / response curve	No plot of concentration/response curve given in report.	
4.1.10	Other effects	None	
4.2	**Results of controls**		
4.2.1	Number/ percentage of plants showing adverse effects	See Tables A7_5_1_3-6a and A7_5_1_3-6b	
4.2.2	Nature of adverse effects	Not relevant	
4.3	**Test with reference substance**	Not performed	
4.3.1	Concentrations	-	
4.3.2	Results	-	

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Test according to OECD Guideline 208 (Proposal for Updating Guideline 208, Draft Document, July 2000): Seedling Emergence and Seedling Growth Test. Test was performed for 21 days in a growth chamber under controlled test conditions with three plant species: *Brassica napa, Glycine max,*

Section A7.5.1.3 Acute toxicity to terrestrial plants (1)

Annex Point IIIA, XIII 3.4 ***Brassica napuss, Avena sativa, Glycine max***

		Avena sativa.
		Effective concentrations were calculated based on fresh weight.
5.2	**Results and discussion**	
5.2.1	EC_{20}	Not described
5.2.2	EC_{50}	Based on fresh weight: *Brassica napa:* EC_{50} = 27.67 (24.19-32.25) mg a.i./kg soil; *Avena sativa:* EC_{50} = 51.30 (38.43-64.80) mg a.i./kg soil ; *Glycine max:* EC_{50} = 83.34 (0.07-603.17) mg a.i./kg soil
5.2.3	EC_{80}	Not described
5.3	**Conclusion**	There is a clear dose-response relationship for all 3 plants.
		The test can be considered valid, as the minimum germination rate of the control seeds was 70 % and the controls exhibit normal growth. There were no visible phototoxic effects
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[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	10/11/06
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ... *(specify)*
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_5_1_3-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	Not applicable since water solubility of thiacloprid is about 0.185 g/l at 20°C (Krohn, 1996)
Vehicle	Not applicable since water solubility of thiacloprid is about 0.185 g/l at 20°C (Krohn, 1996)
Concentration of vehicle	-
Vehicle control performed	-
Other procedures	-

Table A7_5_1_3-2: Dilution water

Criteria	Details
Source	Not applicable, no dilution with water
Alkalinity / Salinity	-
Hardness	-
pH	-
Oxygen content	-
Conductance	-
Holding water different from dilution water	-

Table A7_5_1_3-3: Test plants

	Family	Species	Common name	Source (seed/plant)
Dicotyledonae	Brassicaceae	***Brassica napus***	Oilseed Rape	Source not mentioned in report
	Leguminoseae	***Glycine max***	Soybean	
Monocotyledonae	Gramineae	***Avena sativa***	Oat	Source not mentioned in report

Table A7_5_1_3-4: Test system

Criteria	Details
Test type	Test was performed in a growth chamber under controlled test conditions. Parameters measured were fresh weight, germination, mortality, phytotoxicity and growth stage
Container type	Commercial plastic flower pots Size of pots: 12 cm diameter for *Avena sativa* or 14 cm diameter for *Brassica napa* and *Glycine max*
Seed germination potential	Germination rate in the study (mean of controls): *Brassica napa*: 95 %, *Glycine max*: 100 %, *Avena sativa*: 95 %
Identification of the plant species	Each test unit was uniquely identified with at least study number, treatment and replicate number
Number of replicates	8 pots per treatment group were tested
Numbers of plants per replicate per dose	Each pot contained 5 seeds; in total 40 seeds per treatment group were tested.
Date of planting	Experimental starting date: 2005-04-22
Plant density	Each pot contained 5 seeds; Size of pots: 12 cm diameter for *Avena sativa* or 14 cm diameter for *Brassica napa* and *Glycine max*
Date of test substance application	Experimental starting date: 2005-04-22
High of plants at application	The test seeds were sowed in soil incorporated with the test item
Date of phytotoxicity rating or harvest	- Visual phytotoxicity ratings (e.g. chlorosis, necrosis, abnormal growth): Days 7, 14 and 21 - Fresh weight: at the end of the test (Day 21) - Germination: Days 7, 14 and 21 - Mortality: at the end of the test (Day 21) - Growth stages: Were reported according to BBCH-Monograph-Growth stages: at day 21 Experimental completion date: 2005-05-13
Dates of analysis	2005-04-27 (analytical verification of the stock solution: 80 % recovery)

Table A7_5_1_3-5: Test conditions

Criteria	Details
Test type	Terrestrial plants, seedling emergence and seedling growth test according to OECD guideline 208
Method of application	The test substance was mixed with fine quartz sand (3.3% w/w) and then applied with this mixture to the soil. Treatment of the control: The same amount of untreated quartz sand was mixed into the soil
Application levels	The dosages of the test substance were: 4.1, 10.2, 25.6, 32.6, 45.7, 64.0, 89.6, 125.4, 160.0, 400.0, 1000.0 mg/kg soil dw *Brassica napus:* 4.1, 10.2, 25.6, 64.0, 160 mg/kg soil dw *Avena sativa:* 32.6 to 125.4 mg/kg soil dw *Glycine Max:* 32.6, 45.7, 64.0, 89.6, 125.4 mg/kg soil dw
Dose rates	Dose rates: See above; Application scheme: 1. control, 2. test substance (increasing concentrations)
Substrate characteristics	The soil was delivered and analysed by LUFA Speyer, Germany. Soil Type (USDA): Sandy loam (LUFA soil 2.3); Particle size: All particles smaller than 0.2 mm; Organic carbon (%): 1.02 ± 0.2 %; pH 6.3 ± 0.2
Watering of the plants	After sowing the pots were placed saucers and watered. Bottom watering (through saucers) was done where necessary after a daily spot check.
Temperature	The test plants were grown at 24.4 °C (range 22.7-26.9 °C) during daytime and 18 °C (range 17.1-19.7 °C) at night.
Thermoperiod	See above
Light regime	Light regime: 16 hours light : 8 hours dark; Light intensity: 8326 (5130-13540) lux
Relative humidity	Day: 54.6 % (range 38.8-66.0 %); Night 75.6 % (range 47.2-86.6 %)
Wind volatility	Not mentioned in report

Table A7_5_1_3-5: Test conditions (continued)

Criteria	Details
Observation periods and duration of test	- Visual phytotoxicity ratings (e.g. chlorosis, necrosis, abnormal growth): Days 7, 14 and 21 - Fresh weight: at the end of the test (Day 21) - Germination: Days 7, 14 and 21 - Mortality: at the end of the test (Day 21) - Growth stages: Were reported according to BBCH-Monograph-Growth stages: at day 21 Test duration: 21 days
Pest control	Not applicable
Any other treatments and procedures	Fertilizer was given one to three times per week: 1 g/l Flory 9 Hydro (Planta) + 0.023 g/l Fetrilon (Compo)

Table A7_5_1_3-6a: Effective phytotoxicity after test termination (Part 1)

Species	Treatment Group*	Germination (%)	Mortality (%)	Fresh weight (g)	SD**	Effect *** (%)	Statistics
		Day 21	Day 21	Day 21			
Brassica napus	Control						
	4.1						
	10.2						
	25.6						
	64						
	160						
Avena sativa	Control						
	32.6						
	45.7						
	64						
	89.6						
	125.4						
Glycine max	Control						
	25.6						
	64						
	160						
	400						
	1000						

* : Nominal test substance concentrations (mg a.i./kg soil)
** : Standard Deviation
*** : negative values indicate reduction compared to control
s. : significant
n.s. : not significant
1 : Multiple comparison Dunnett Test, a = 0.05 (n.s. = not significant)

Table A7_5_1_3-6b: Effective phytotoxicity after test termination (Part 2)

Species	Treatment Group*	Phytotoxicity (%) Day 7	Day 14	Day 21	Growth Stage (BBCH)
Brassica napus	Control				
	4.1				
	10.2				
	25.6				
	64				
	160				
Avena sativa	Control				
	32.6				
	45.7				
	64				
	89.6				
	125.4				
Glycine max	Control				
	25.6				
	64				
	160				
	400				
	1000				

* : Nominal test substance concentrations (mg a.i./kg soil)

Table A7_5_1_3-7: Summary of effect concentrations *(based on fresh weight)*

		NOEC	LOEC	Statistical Analysis	EC_{50}	Statistical Analysis
Species	**Confidence limit (c.l.)**	(mg a.i./kg soil)			(mg a.i./kg soil)	
Brassica napus		[redacted]	[redacted]	1	[redacted]	2
	lower 95 % c.l.				[redacted]	
	upper 95 % c.l.				[redacted]	
	r^2				[redacted]	
Avena sativa		[redacted]	[redacted]	1	[redacted]	2
	lower 95 % c.l.				[redacted]	
	upper 95 % c.l.				[redacted]	
	r^2				[redacted]	
Glycine max		[redacted]	[redacted]	1	[redacted]	2
	lower 95 % c.l.				[redacted]	
	upper 95 % c.l.				[redacted]	
	r^2				[redacted]	

1 : Multiple comparison Dunnett Test, a = 0.05
2 : Probit Analysis

A7.5.2.1
Annex Point IIIA XIII 3.2

Reproduction study with other soil non-target macro-organisms (1)

Field study

Official use only

1 REFERENCE

1.1	**Reference**	Heimbach, F. (1997d *[Monograph: 1997b]*): Effects of YRC SC 480 on the earthworm fauna of a grassland area. Bayer AG, Report No.: HBF/RgF 40, date: 1997-05-13. *PPP-Monograph Chapter: B.9.6 Effects on earthworms. B.9.6.1 Toxicity – plant protection product (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; ISO draft guideline CD 11268-3; German BBA guideline Part VI 2-3	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	

3 MATERIALS AND METHODS

X

A field study on the effect of 'YRC 2894 SC 480' (purity: [redacted] g thiacloprid /L) on earthworms was performed. Spray applications were made to a grassland area (in Monheim, Germany) with a natural earthworm fauna. There were 4 plots (of 10 m x 10 m) per application rate, which were 300 g (=125 g a.s.) and 600 g (=250 g a.s.) product/ha (in 600 l water/ha). The product was applied twice (first: 9th May, second: 31st May, both shortly after mulching) with a three week interval. There were also 4 plots for a reference substance (benomyl) which was applied once on 9th May, and there were also 4 untreated control plots. The earthworm abundances were determined (using formalin extraction) 7 weeks after the first application (26-30th June), at the end of the season in autumn 1995 (23-30th October), and again in spring 1996 (15-19th April) approximately one year after application.

The earthworm abundance was high: up to 329 earthworms/m^2 had been sampled in autumn 1995. Six different species were identified: the tanylobous species *Lumbricus terrestris*, *L. rubellus* and *L. castaneus*, the epilobous species *Aporrectodea caliginosa*, *Allolobophora chlorotica* and *Aporrectodea longa*.

A7.5.2.1
Annex Point IIIA XIII 3.2

Reproduction study with other soil non-target macro-organisms (1)

Field study

4 RESULTS

Neither application rate caused a statistically significant increase or reduction in earthworm numbers or biomass 7 weeks after the first application. This was with the exception of a significant reduction of adult *L. castaneus* (p=0.05). This was not dose related and could be explained by natural variations in populations. Similar results were obtained in autumn 1995 (4 months after application): the number and biomass of *L. terrestris* was significantly reduced at the lower application rate, whereas the number of other tanylobous species was higher than in the control plots. The higher application rate did not show any significant effect at this time as well as in the following spring, neither for adults or juvenile earthworm numbers or biomass nor for the sum of adults and juveniles. The number of adult *L. terrestris* in spring 1996 was still significantly reduced at the lower application rate. However, at the higher application rate there were more adult *L. terrestris* in the treated plots than the controls. X

The reference substance (benomyl) reduced earthworm abundance by approximately 70%, 7 weeks after application.

Considering the variability of earthworm abundances in natural soils, it was concluded that this study indicated that earthworm populations were not negatively affected by either application rate of 'YRC 2894 SC 480' (2 x 300 g formulation/ha or 2 x 600 g formulation/ha).

5 CONCLUSION

5.1 Conclusion

The test substance is a thiacloprid-containing plant protection product. [redacted] The concentrations studied are nominal values, since analytical measurements of the substrate are not specified in the test guideline. 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	17/11/06
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 A7.5.2.1
Annex Point IIIA XIII 3.2

Reproduction study with other soil non-target macro-organisms (2)

Eisenia fetida

Official use only

1 REFERENCE

1.1	**Reference**	Heimbach, F. (1995e *[Monograph: 1995a]*): Influence of YRC 2894 SC 480 on the reproduction of earthworms (*Eisenia fetida*). Bayer AG, Report No.: HBF/Rg 212, date: 1995-04-06. *PPP-Monograph Chapter: B.9.6 Effects on earthworms. B.9.6.1 Toxicity – plant protection product (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; ISO/DIS 11268-2; German BBA guideline Part VI, 2-2	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	

3 MATERIALS AND METHODS

In a laboratory study on the effects of 'YRC 2894 SC 480' (purity: [redacted] g thiacloprid /L) on earthworm reproduction, 40 adult earthworms (*Eisenia fetida / Eisenia andrei*) per test concentration (4 replicates each containing 10 adults) were exposed for 56 days following single spray applications (to soil surface, without soil mixing) of 62.5, 125, 250, 625 and 1250 g a.s./ha applied with 800 l water/ha. Mortalities and body weight of the adults were recorded on day 28. Number of offspring and biomass of offspring were noted on day 56. Measured water content of the test soil was 33% at the start and 29% at the end of the study. X

4 RESULTS

There was no mortality of adults at any test level. There was a moderate reduction of body weight at exposure levels from 62.5 to 250 g as/ha. At the higher exposure levels body weight was more severely reduced. Reproduction rate was statistically significantly reduced at all exposure levels. Total biomass of offspring was statistically significantly reduced at the two highest application rates compared with the control. The NOEC was <62.5g a.s./ha (the lowest test level). X

Results are presented in Table A7_5_1_2-1.

Section A7.5.2.1
Annex Point IIIA XIII 3.2

Reproduction study with other soil non-target macro-organisms (2)

Eisenia fetida

5 CONCLUSION

5.1	**Conclusion**	The test substance is a thiacloprid-containing plant protection product. [redacted]. However, a NOEC for sublethal effects could not be determined as the lowest concentration tested.	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 17/11/06

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	

Table A7_5_1_2-1 Results of a reproduction study on earthworms using 'YRC 2894 SC 480'

Test species	*Eisenia fetida* (adults)					
Exposure	spray application on soil surface					
Test formulation	control	'YRC 2894 SC 480'				
Application rate (g a.s./ha)	-	62.5	125	250	625	1250
Adults: Mortality						
Mean weight alteration after 28d relative to starting weight						
Offspring: Mean number per adult after 56 days						
Percentage number of juvenile worms compared with the control.						
Mean total weight of offspring per adult						

* statistically significant compared with the control (P=0.05)

Section A7.5.2.1
Annex Point IIIA XIII 3.2

Reproduction study with other soil non-target macro-organisms (4)

Metabolite M02

Folsomia candida (Collembola, arthropod)

Official use only

1 REFERENCE

1.1	**Reference**	Nienstedt, K. M.(2001): Reproduction toxicity exposing *Folsomia candida* to YRC 2894-amide. Spingborn Lab., Horn, Switzerland. Bayer AG, Report No. 1022.019.641, date: 2001-08-21. *Addendum 1 to PPP-Monograph; Chapter: B.9.4 Metabolites M02 (YRC 2894-amide; KKO 2254) and M30 (YRC 2894 sulfonic acid, sodium salt; WAK 6999). B.9.4.3 Effects on soil non-target macro-organisms – M02*
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 11267 Soil Quality – Inhibition of reproduction of Collembola (*Folsomia candida*) by soil pollutants, 1999
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

A 28-day study with *Folsomia candida* was undertaken with the metabolite M02 purity: [redacted] The metabolite was dissolved in acetone and applied on quartz sand that was mixed with the artificial soil. The toxic standard was Betanal/kg. A total of 10 *Folsomia candida* (10 - 12 days old) per replicate (5) were exposed to 1, 10, and 100 mg test item/kg artificial soil at 20°C ± 2°C and 16 hour light to 8 hour dark cycle with 400-800 Lux. Mortality and reproduction were determined after 28 days.

4 RESULTS

In a reference test with the toxic standard, the number of juveniles was statistically significantly reduced in comparison to the control by the toxic standard. Therefore, the observed effects of the toxic standard indicate a high sensitivity of the test system.

The results are summarised in Table A7_5_1_2-1.

Section A7.5.2.1
Annex Point IIIA XIII 3.2

Reproduction study with other soil non-target macro-organisms (4)

Metabolite M02

Folsomia candida (Collembola, arthropod)

5 CONCLUSION

5.1	Conclusion	[redacted] The concentrations studied are nominal values, since analytical measurements of the substrate are not specified in the test guideline. [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	17/11/06
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	

Table A7_5_1_2-1 **Effects of M02 on Mortality and Reproduction of *Folsomia candida***

Test object: *Folsomia candida* Exposure: Artificial soil, 28 d		
	Adult mortality	Reproduction
LOEC	>100	100
LC_{50}/EC_{50} [mg test item/kg]	not applicable	not applicable
NOEC [mg test item/kg]	100	10

Section A7.5.2.1
Annex Point IIIA XIII 3.2

Reproduction study with other soil non-target macro-organisms (5)

Metabolite M30

Folsomia candida (Collembola, arthropod)

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1 REFERENCE

1.1	**Reference**	Moser, T.; Scheffczyk, A. (2002): Thiacloprid-sulfonic acid Na-salt: Acute and reproduction to the collembolan species *Folsomia candida*. ECT GmbH, Floersheim, Germany. Bayer AG, Report No. P38CR, date: 2002-03-13. *Addendum 1 to PPP-Monograph; Chapter: B.9.4 Metabolites M02 (YRC 2894-amide; KKO 2254) and M30 (YRC 2894 sulfonic acid, sodium salt; WAK 6999). B.9.4.3 Effects on soil non-target macro-organisms – M30*	
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 11267 Soil Quality – Inhibition of reproduction of Collembola (*Folsomia candida*) by soil pollutants, 1999
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

A 28-day study with *Folsomia candida* was undertaken with the metabolite M30 purity: [redacted]%. The metabolite was mixed with the artificial soil. The toxic standard was Betanal/kg. A total of 10 Folsomia candida (10 - 12 days old) per replicate (5) were exposed to 10, 31.6, 100, 316 and 1000 mg test item/kg artificial soil at 18°C – 21°C and 554 Lux and were fed weekly with granulated dry yeast. Mortality and reproduction were determined after 28 days.

4 RESULTS

It should be noted that the juveniles at the highest concentration of 1000 mg test item/kg soil were clearly smaller than in the control and all other test concentrations.

In a reference test with the toxic standard, the number of juveniles was statistically significantly (U-test according to Mann-Whitney, $p \leq 0.05$) reduced to 25% in comparison to the control by the toxic standard. Therefore, the observed effects of the toxic standard indicate a high

Section A7.5.2.1
Annex Point IIIA XIII 3.2

Reproduction study with other soil non-target macro-organisms (5)

Metabolite M30

Folsomia candida (Collembola, arthropod)

sensitivity of the test system.

The results are summarised in Table A7_5_1_2-1.

5 CONCLUSION

5.1 Conclusion

[redacted]. The concentrations studied are nominal values, since analytical measurements of the substrate are not specified in the test guideline. [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	17/11/06
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

Table A7_5_1_2-1 **Effects of M30 on Mortality and Reproduction of *Folsomia candida***

Test object: *Folsomia candida* Exposure: Artificial soil, 28 d		
	Adult mortality	Reproduction
LC_{50}/EC_{50} [mg test item/kg]	not applicable	not applicable
NOEC [mg test item/kg]	1000	1000

Section A7.5.1.2
Annex Point IIIA XIII 3.2

Reproduction study with other soil non-target macro-organisms (3)

Eisenia fetida andrei

			Official use only
		1 REFERENCE	
1.1	**Reference**	Luehrs, U. (2003): Thiacloprid SC 480: Effects on Reproduction and Growth of Earthworms *Eisenia fetida* in Artificial Soil. IBACON unpublished report No. 16661022, date: 2003-05-09. *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; German BBA 1994: 'Effects of pesticides on the reproduction and growth of *Eisenia fetida / Eisenia andrei*'. In: BBA (Biologische Bundesanstalt für Land- und Forstwirtschaft, Bundesrepublik Deutschland), Richtlinie für die Prüfung von Pflanzenschutzmitteln im Zulassungsverfahren, Teil VI, Nr. 2-2; C. Kula ISO-Guideline 11268-2, "Soil quality - Effects of pollutants on earthworm (*Eisenia fetida*) - Part 2: „Determination of effects on reproduction", International Organization for Standardization, 1998	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 METHOD	
3.1	**Test material**	Thiacloprid SC 480	
3.1.1	Lot/Batch number	Batch Number [redacted]	
3.1.2	Specification	Active ingredient: as given in section 2 of the dossier	
3.1.3	Purity	Not applicable	X
3.1.4	Composition of Product	480 g/l of active substance (thiacloprid)	
3.1.5	Further relevant properties	Product in water miscible	
3.1.6	Method of analysis	No analytical monitoring in the biological test	
3.2	**Reference substance**	Yes; Derosal SC 360 (active ingredient: carbendazim) Test performed at least once a year in the IBACON testing facilities. In the most recent test at that moment carbendazim showed significant	

Section A7.5.1.2 Annex Point IIIA XIII 3.2

Reproduction study with other soil non-target macro-organisms (3)

Eisenia fetida andrei

		effects on reproduction.	
3.2.1	Method of analysis for reference substance	No data	X
3.3	**Testing procedure**		
3.3.1	Preparation of the test substance	Stock solutions: Two stock suspensions were prepared by suspending 233 mg of Thiacloprid SC 480 in 1000 g of deionised water (stock 1) and 262 mg product in 2000 g of deionised water (stock 2). Test solutions: Stock 1 and stock 2 were the highest used test concentrations. Test concentrations 1-3 were prepared by diluting the second stock suspension in three steps by adding 700 g of deionised water to 900 g of this suspension or the previous dilution. To reach a homogenous emulsion a magnetic stirrer was used.	
3.3.2	Application of the test substance	All dilutions were applied in a singular application with a laboratory-spray equipment onto the soil of the assigned trays. The inner sides of the test container walls were covered with plastic covers to protect the inside walls. The covers were removed immediately after spraying the trays. Application was done after the introduced test organisms had burrowed into the soil. After application containers were left open for ca. 1 hour following treatment, care was taken to prevent worms from escaping during this time; afterwards the containers were closed with the lids. Application rate: 6 mg/cm^2 ± 10 % (corresponding to 600 L spray liquid/ha).	
3.3.3	Test organisms	See Table A7_5_1_2-2	
3.3.4	Test system	See Table A7_5_1_2-3	
3.3.5	Test conditions	See Table A7_5_1_2-4	
3.3.6	Test duration	56 days	
3.3.7	Test parameter	Mortality, body weight , feeding activity and reproduction of adults	
3.3.8	Examination	Adult worms were exposed during four weeks, after which the test substrate was emptied onto a tray and adult worms were counted, removed and weighed per replicate after they were washed under tap water and dried on filter paper. Then the substrate minus the adult worms was returned to the respective test units. Offspring were exposed for another 4 weeks. Young worms were removed by placing the test units in a water bath at ca. 60 °C and counting all emerging worms. In addition afterwards the soil of each container was emptied out onto a tray and checked by hand for remaining young worms.	
3.3.9	Monitoring of test substance concentration	No	X

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Annex Point IIIA XIII 3.2

Reproduction study with other soil non-target macro-organisms (3)

Eisenia fetida andrei

3.3.10	Statistics	Data of mortality were analysed for significance by using Fischer-exact test (two-sided, a = 0.05). Data of body weight changes and reproduction were tested for normal distribution and homogeneity of variance using Kolmogoroff-Smirnov test and Cochran test. Because data of body weight changes and reproduction were normally distributed and homogeneous Dunnett test was used (multiple comparison, two-sided, a = 0.05). The software used to perform the statistical analysis was SYSTAT 9 for Windows and ToxRatPro, version 2.07, ToxRat solutions GmbH (1999-2002).
		4 RESULTS
4.1	**Filter paper test**	Not performed
4.1.1	Concentration	-
4.1.2	Number/ percentage of animals showing adverse effects	-
4.1.3	Nature of adverse effects	-
4.2	**Soil test**	
4.2.1	Initial concentrations of test substance	11.7, 20.8, 37.1, 65.8 and 117.5 mL test item/ha artificial soil (dry weight). See also Table A7_5_1_2-3
4.2.2	Effect data (Mortality)	The recorded data on mortality is given in Table A7_5_1_2-5; the ecotoxicological endpoints are reported in Table A7_5_1_2-6.
4.2.3	Concentration / effect curve	Regression curve for Thiacloprid SC 480 was not calculated.
4.2.4	Other effects	For all parameters measured see Table A7_5_1_2-5; the ecotoxicological endpoints are reported in Table A7_5_1_2-6.
4.3	**Results of controls**	
4.3.1	Mortality	See Table A7_5_1_2-5
4.3.2	Number/ percentage of earthworms showing adverse effects	No adverse effects observed
4.3.3	Nature of adverse effects	No adverse effects observed
4.4	**Test with reference substance**	Yes; Derosal SC 360 (active ingredient: carbendazim)
4.4.1	Concentrations	< 4 mg carbendazim /kg (single concentrations not specified)

Section A7.5.1.2
Annex Point IIIA XIII 3.2

Reproduction study with other soil non-target macro-organisms (3)

Eisenia fetida andrei

4.4.2	Results	EC50 = 1.9 mg carbendazim /kg (according to [redacted] the testing facility, this value indicates that the test conditions were adequate)
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	Acute earthworm toxicity of Thiacloprid SC 480 was investigated according to the German BBA guideline and ISO 11268-2. The test animals were exposed to the following concentrations: 11.7, 20.8, 37.1, 65.8 and 117.5 mL test item/ha artificial soil. After 56 days, the number of surviving animals, their weight alteration and the number of juveniles was determined.
5.2	**Results and discussion**	
5.2.1	LC_0	≥ 117.5 mL product/ha
5.2.2	LC_{50}	> 117.5 mL product/ha
5.3	**Conclusion**	The test item did not show effects on mortality, growth, and reproduction of the earthworm. Therefore, the NOEL was determined to be 117.5 mL test item/ha, i.e. the highest rate tested in this study corresponding to 0.233 g test item in 1 L deionised water. The mortality rate in the control was below 10 % which is regarded as the limit for natural mortality. The LC_{50} of the reference substance is within the usual range. The test conditions are therefore equivalent to the standard.
5.3.1	Other Conclusions	-
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	[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	18/11/06
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ... *(specify)*
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_5_1_2-1: Preparation of TS solution

Criteria	Details
Type and source of dilution water	deionised water
Alkalinity / Salinity	-
Hardness	-
PH	-
Oxygen content	-
Conductance	-
Holding water different from dilution water	No

Table A7_5_1_2-2: Test organisms

Criteria	Details
Species/strain	*Eisenia fetida Andrei*
Source of the initial stock	Laboratory culture of IBACON
Culturing techniques	They were bred under standardised conditions in a breeding medium of cattle manure, peat, sand and straw, fed with cattle manure, stored at room temperature.
Age/weight	The adult worms used in the test were ca. 10 months old with well developed clitellum, age range between test individuals not differing for > 4 weeks. The average weight of the animals at test begin was 300 mg – 500 mg
Pre-treatment	The earthworms were removed from the breeding substrate for acclimatisation and kept in the test substrate (without test substance) under the test conditions during one day

Table A7_5_1_2-3: Test system

Criteria	Details
Artificial soil test substrate	The test substrate consists of : - 10 % Sphangnum-peat, air-dried and finely ground (2 mm) - 20 % Kaolin clay (kaolinite content > 30 %) - Approximately 0.5 % chalk ($CaCO_3$) added to adjust pH to 6.0 ± 0.5. - Approximately 69.5 % fine quartz (F34) containing more than 50 % by mass of particle size 0.05 mm to 0.2 mm. Water capacity of the artificial soil: 50.24 % of the dry weight
Test mixture	11.7, 20.8, 37.1, 65.8 and 117.5 mL test item/ha artificial soil.
Size, volume and material of test container	Plastic boxes (18.3 cm x 13.6 cm x 6 cm with the size of ca. 16.5 cm x 11.5 cm = 189.75 cm^2 at the level of the soil), with perforated transparent lids to enable exchange of air, to minimise evaporation of the artificial soil, and to prevent the worms from escaping.
Amount of artificial soil (kg)/ container	Each container was filled with 643.6 g of the prepared soil (approximately 500 g (dry weight) artificial soil, plus approximately 138.6 g water, plus approximately 5 g food). The height of the soil layer in the container was 5-6 cm.
Nominal levels of test concentrations	0.023, 0.041, 0.074, 0.131, 0.233 g test substance/L deionised water
Number of replicates/concentration	4
Number of earthworms/test concentration	40
Number of earthworms/container	10
Light source	Laboratory lamp
Test performed in closed vessels due to significant volatility of test substrate	No

Table A7_5_1_2-4: Test conditions

Criteria	Details
Test temperature	Acclimatisation: 19 °C Exposure: 18-20 °C
Moisture content	Range moisture content in substrate [%] / [% of max. water holding capacity]: Start of study: 27.4-28.2 / 54.5-56.1; End of study: 27.1-29.4 / 53.9-58.5
pH	Start of study: 6.1-6.2; End of study: 6.2-6.3
Adjustment of pH	Yes; Around 0.5 % chalk ($CaCO_3$) was added to the test substrate to adjust the pH value to 6.0 ± 0.5
Light intensity / photoperiod	16 h light: 8 h dark 527-699 lux
Relevant degradation products	Degradation products were not investigated in this study.

Table A7_5_1_2-5: Results of the test on reproduction (means of n = 4 test containers, each containing 10 earthworms)

Test formulation	control	'Thiacloprid SC 480'				
Nominal Test Substance Concentration [mL Thiacloprid SC 480 /ha]	-	**11.7**	**20.8**	**31.7**	**65.8**	**117.5**
	Mean results ± SD (Standard deviation from 4 replicates)					
Mortality	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Body weight change	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Reproduction of juveniles: - No. of juveniles - % of control	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Amount of food added [g]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

* Not significantly different compared to the control

Table A7_5_1_2-6: Effect data after 56 days (nominal concentrations)

		[mL test item/ha] / [g thiacloprid/L]
LC_{50}		> 117.5 / 0.233
LLC	Lowest lethal conc.	> 117.5 / 0.233
LOEC	Lowest observed effect concentration	> 117.5 / 0.233
NOEC (LC_0)	No-observed-effect-concentration	≥ 117.5 / 0.233

Table A7_5_1_2-7: Validity criteria for acute earthworm test according to OECD Guideline 207

	fulfilled	Not fulfilled
Mortality of control animals < 10%	X	

Section 7.5.2.2 Annex Point IIIA 13.3	Long-term test with terrestrial plants	
	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 specific long term test on terrestrial plants is not available for thiacloprid. An agreed guideline is still missing. Such a test is not regarded to be necessary in the scope of the evaluation of thiacloprid due to its rapid degradation in this medium (soil DT_{90} = 21.7-29 days). Furthermore, the use of thiacloprid in the plant protection area during about 20 years indicates thiacloprid will not cause long term plant damages at the applied concentrations.	
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	08/08/06	
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 A7.5.3.1.1 Acute oral toxicity on birds (1)

Annex Point IIIA XIII 1.1 *Colinus virginianus* (Bobwhite quail)

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] 1995a *[Monograph: 1995c]*): YRC 2894 techn. Acute oral toxicity to bobwhite quail [redacted] Report No.: VB-036, date: 1995-09-07, *revised 1998-09-21.* *PPP-Monograph Chapter: B.9.1 Effects on birds, B.9.1.1 Acute oral toxicity - Active substance (Table 9.2_ 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]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes; US-EPA guideline 71-1
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

Thiacloprid, purity: [redacted]%, single oral administration in gelatine capsules to adult Bobwhite quail, *Colinus virginianus* (21-week-old, 10 birds (5f, 5m)/ per concentration): 152, 289, 551, 1050 or 2000 mg as/kg bw and control; dosing was followed by a subsequent observation period of 14 days.

Adverse effects on behaviour were recorded as well as effects on feed consumption. Additionally, gross pathological changes at study termination from the 2000 mg as/kg bw treatment level were determined.

4 RESULTS

The LD_{50} for Bobwhite quail was determined to be 2716 mg ai/kg bw. The NOEL was 152 mg a.i./kg bw, based on dose dependent symptoms (diarrhea) and reduced food consumption in the 289 mg /kg dose level. Symptom in higher dose level was also apathy. No gross pathological changes in body organs.

Section A7.5.3.1.1 **Acute oral toxicity on birds (1)**

Annex Point IIIA XIII 1.1 *Colinus virginianus* (Bobwhite quail)

5 CONCLUSION

5.1 Conclusion [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	07/08/06
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 A7.5.3.1.1 Acute oral toxicity on birds (2)

Annex Point IIIA XIII 1.1 *Coturnix coturnix japonicus* (Japanese quail)

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] 1994): YRC 2894 (technical grade), acute oral toxicity to Japanese quail, range finding test [redacted] Report No. VW-166, date: 1994-03-17. *PPP-Monograph Chapter: B.9.1 Effects on birds, B.9.1.1 Acute oral toxicity - Active substance (Table 9.2_ 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]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	No; Range finding study. Internal test method comparable to US-EPA § 71-1
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

Japanese quails (*Coturnix coturnix japonicus*) were given a single oral administration of thiacloprid ([redacted] %) in gelatine capsules: 5, 15, 30 or 60 mg as/kg bw (6 quails per test concentration with 3 males and 3 females). The birds were observed for 14 days.

4 RESULTS

The LD_{50} value was determined to be 49 mg ai/kg bw and the no observed effect dose (NOEL) = 15 mg ai/kg bw.

5 CONCLUSION

5.1	**Conclusion**	[redacted] the Japanese quail seems to be more sensitive.

Section A7.5.3.1.1 Acute oral toxicity on birds (2)

Annex Point IIIA XIII 1.1 *Coturnix coturnix japonicus* (Japanese quail)

[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	07/08/06
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	