[redacted]

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[redacted]

[redacted]

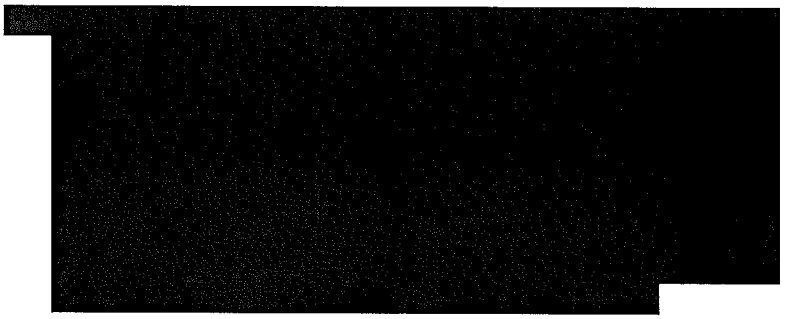
[redacted]

[redacted]	[redacted]			
	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

Section A7.2.2.1 Annex Point IIIA, VII.4, XII.1.1, XII.1.4	Aerobic degradation in soil, further studies: The rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions
	JUSTIFICATION FOR NON-SUBMISSION OF DATA Official use only
	Other justification
Detailed justification:	According to the TNsG on data requirements, further laboratory studies on aerobic degradation in at least three soil types are required if the DT_{50lab} determined according to paragraph A7.2.1 above is more than 21 days and the PEC/PNEC > 1 for soil, or there is danger for the groundwater or other refinement of the preliminary risk assessment for soil is necessary. [redacted] [redacted] Therefore, additional laboratory studies on aerobic degradation of IPBC in at least three soil types are not regarded to be warranted.
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.2.2.2 Annex Point IIIA, XII.1.1, Annex VI, para 85	Aerobic degradation in soil, further studies: Field soil dissipation and accumulation
	JUSTIFICATION FOR NON-SUBMISSION OF DATA Official use only
	Other justification
Detailed justification:	According to the TNsG on data requirements, the soil dissipation study should provide estimates of the time taken for dissipation of 50 % and 90 % of the active substance under field conditions. Field soil accumulation test are required in two soil types if the $DT_{90\ field}$ is over one year and the $DT_{50field}$ is greater than 3 months, or if during laboratory test non-extractable residues are formed in amounts exceeding 70 % of the initial dose after 100 days with a mineralisation rate of less than 5 % in 100 days.  Therefore, further field soil dissipation and accumulation are not deemed necessary.
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.2.2.3 Annex Point IIIA, XII.1.4	Aerobic degradation in soil, further studies: Extent and nature of bound residues
	JUSTIFICATION FOR NON-SUBMISSION OF DATA Official use only
	Other justification
Detailed justification:	According to the TNsG on data requirements, information on extent and nature of bound residues are required if the results in accordance with paragraph A7.2.1 or A7.2.2.1 indicate that bound residues may be formed which account for more than 10 % of the active substance added [redacted]  Therefore, sufficient information on the extent and nature of bound residues are available and no further studies are deemed necessary.
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.2.2.4 Annex Point IIIA, XII.1.1	Aerobic degradation in soil, further studies: Other soil degradation studies
	JUSTIFICATION FOR NON-SUBMISSION OF DATA — Official use only
	Other justification
Detailed justification:	[redacted] Therefore, no other soil degradation studies are deemed necessary.
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.2.3.1/01
Annex Point IIIA, XII.1.2

Adsorption and desorption in at least three soil types and, where relevant, the adsorption and desorption of metabolites and degradation products

			Official use only
		1 REFERENCE	
1.1	**Reference**	Schimmelpfennig, H. (2004): Estimation of the K_{OC} of the IBPC degradation product PBC using the PCKOC program (v.1.66); Scientific Consulting Company, Chemisch-Wissenschaftliche Beratung GmbH, 55234 Wendelsheim, Germany; Doc. No. 731-004; 20.03.2004; (unpublished)	
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**	Not applicable; model calculation according	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	Not applicable.	
		3 MATERIAL AND METHODS	
3.1	**Test material**	Not applicable.	
3.2	**Reference substance**	[redacted]	
3.3	**Test solution**	[redacted]	
3.4	**Testing procedure**	The K_{OC} of PBC was estimated with the programme PCKOC v1.66 for Microsoft Windows 3.1, Windows 95/98, Windows NT (© 2000 US Environmental Protection Agency).	
		4 RESULTS	
4.1	**K_{OC}**	The K_{OC} of PBC was calculated to be 198.1 mL/g	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The K_{OC} of IPBC degradation product PBC was evaluated based on calculations performed with PCKOC v1.66.	

5.2	**Results and discussion**	The K_{OC} of PBC was calculated to be 198.1 mL/g
5.3	**Conclusion**	[redacted]
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	No

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.2.3.2 Annex Point IIIA, XII.1.3	Adsorption and mobility in soil, further studies: Mobility in at least three soil types and, where relevant, the mobility of metabolites and degradation products
	JUSTIFICATION FOR NON-SUBMISSION OF DATA — Official use only
	Other justification
Detailed justification:	[redacted] Therefore, no lysimeter study is deemed necessary.
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.3.1/01 Phototransformation in air (estimation method)

Annex Point IIIA, VII.5

Official use only

1 REFERENCE

1.1	**Reference**	Görg, J. (2004): Estimation of photochemical degradation of IPBC using the Atkinson calculation method; Scientific Consulting Company, Chemisch-Wissenschaftliche Beratung GmbH, 55234 Wendelsheim, Germany; Doc. No. 743-001; 04.03.2004; (unpublished)
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**	Not applicable; model calculation according to the Atkinson calculation method.
2.2	**GLP**	[redacted]
2.3	**Deviations**	Not applicable.

3 MATERIAL AND METHODS

3.1	**Test material**	Not applicable
3.2	**Reference substance**	[redacted]
3.3	**Test solution**	[redacted]
3.4	**Testing procedure**	[redacted]

Section A7.3.1/01 Phototransformation in air (estimation method)

Annex Point IIIA, VII.5

4 RESULTS

4.1 OH radical reaction rate constant k_{OH}

[redacted]

4.2 Ozone reaction rate constant k_{Ozone}

[redacted]

4.3 Atmospheric half-life using k_{OH}

[redacted]

4.4 Atmospheric half-life using k_{Ozone}

[redacted]

Section A7.3.1/01 Phototransformation in air (estimation method)

Annex Point IIIA, VII.5

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The photochemical and oxidative decomposition of IPBC in air was evaluated based on theoretical grounds by a calculation according to Atkinson.
5.2	**Results and discussion**	
5.2.1	**Reaction rate constant**	$k_{OH} = 25.5485 \times 10^{-12}$ cm^3 molecule^{-1} sec^{-1}. $k_{Ozone} = 42.0 \times 10^{-22}$ cm^3 molecule^{-1} sec^{-1}.
5.2.2	**Tropospherical half life**	The DT_{50} for IPBC in air was estimated to be 5.024 hours using k_{OH}. The DT_{50} for IPBC in air was estimated to be 2728 days using k_{Ozone}.
5.3	**Conclusion**	[redacted]
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	No

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*

Section A7.3.1/01 Phototransformation in air (estimation method)

Annex Point IIIA, VII.5

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 A7.3.2 Annex Point IIIA, XII.3	Fate and behaviour in air, further studies	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	According to the TNsG on data requirements an experimental estimation of the fate and behaviour in air is only required if the active substance is to be used in preparations form fumigants or causes risk to the atmospheric environment. [redacted] Therefore, no experimental estimation of the fate and behaviour if IPBC in air is deemed necessary.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.4.1.1/01 Acute toxicity to fish

Annex Point IIA, VII.7.1 Fathead Minnow (*Pimephales promelas*)

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (1994): Acute Toxicity of Omacide® IPBC to the Fathead Minnow, *Pimephales promelas*; [redacted] 26.09.1994	
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 U.S. EPA-FIFRA 72-1, which is comparable to OECD 203	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	No	
		3 MATERIAL AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	As given in Section 2. The purity of the test substance was slightly lower than the specification given in section 2. This does not influence the integrity of the study.	
3.1.3	Purity	[redacted]	
3.1.4	Description of test substance	[redacted]	
3.1.5	Composition of Product	[redacted]	
3.1.6	Further relevant properties	[redacted]	
3.1.7	Method of analysis	[redacted]	

Section A7.4.1.1/01 Acute toxicity to fish

Annex Point IIA, VII.7.1 Fathead Minnow (*Pimephales promelas*)

3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Testing procedure**	
3.4.1	Dilution water	[redacted]
3.4.2	Test organisms	Fathead Minnow (*Pimephales promelas*). [redacted]
3.4.3	Test system	[redacted]
3.4.4	Test conditions	[redacted]
3.4.5	Duration of the test	[redacted]
3.4.6	Test parameter	[redacted]
3.4.7	Sampling	[redacted]
3.4.8	Monitoring of TS concentration	[redacted]
3.4.9	Statistics	[redacted]
	4 RESULTS	
4.1	**Limit Test**	[redacted]
4.1.1	Concentration	[redacted]
4.1.2	Number/ percentage of animals showing adverse effects	[redacted]
4.1.3	Nature of adverse effects	[redacted]

Section A7.4.1.1/01 **Acute toxicity to fish**

Annex Point IIA, VII.7.1 Fathead Minnow (*Pimephales promelas*)

4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	[redacted]
4.2.2	Actual concentrations of test substance	[redacted]
4.2.3	Effect data (Mortality)	[redacted]
		[redacted]
4.2.4	Concentration / response curve	[redacted]
4.2.5	Other effects	[redacted]
4.3	**Results of controls**	
4.3.1	Number/ percentage of animals showing adverse effects	[redacted]
4.3.2	Nature of adverse effects	[redacted]
4.4	**Test with reference substance**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test was conducted according to EPA-FIFRA guideline 72-1. It was a flow-through test-system and the fathead minnow (*Pimephales promelas*) was used as test organism.
5.2	**Results and discussion**	[redacted]
5.2.1	NOEC (96 hours)	0.096 mg/L
5.2.2	LC_{50} (96 hours)	0.20 mg/L

Section A7.4.1.1/01 Acute toxicity to fish

Annex Point IIA, VII.7.1 Fathead Minnow (*Pimephales promelas*)

5.2.3	LC_{100} (96 hours)	0.36 mg/L
5.3	**Conclusion**	[redacted] The LC_{50} was calculated to be 0.20 mg/L. The NOEC was determined to be 0.096 mg/L.
5.3.1	Other Conclusions	[redacted]
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	No

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

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.1.1/01-3: Test organisms

Criteria	Details
Species/strain	Fathead minnow (*Pimephales promelas*)
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.1.1/01-4: Test system

Criteria	Details
Test type	Flow-through
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]			
	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

[redacted]

[redacted]

Table A7.4.1.1/01-8: Effect data

	48 h [mg/L][1]	95 % C.L.	96 h [mg/L][1]	95 % C.L.
NOEC	0.096	–	0.096	–
LC_{50}	0.33	0.18 – 0.36	0.20	0.18 – 0.23
LC_{100}	–	–	0.36	–

[1] based on mean measured concentrations

[redacted]

[redacted]

Section A7.4.1.1/02 Acute toxicity to fish

Annex Point IIA, VII.7.1 Sheepshead Minnow (*Cyprinodon variegatus*)

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (1991): Acute Toxicity to the Sheepshead Minnow (*Cyprinodon variegatus*) under Flow-Through Conditions; [redacted] 12.12.1991;
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, U.S. EPA-FIFRA 72-3 which is comparable to OECD 203
2.2	**GLP**	[redacted]
2.3	**Deviations**	No

3 MATERIAL AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section A2. The purity of the test substance was slightly lower than the specification given in section 2. This does not influence the integrity of the study.
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	[redacted]
3.1.5	Composition of Product	[redacted]
3.1.6	Further relevant properties	[redacted]
3.1.7	Method of analysis	[redacted]

Section A7.4.1.1/02 Acute toxicity to fish

Annex Point IIA, VII.7.1 Sheepshead Minnow (*Cyprinodon variegatus*)

3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Testing procedure**	
3.4.1	Dilution water	[redacted]
3.4.2	Test organisms	Sheepshead Minnow[redacted]
3.4.3	Test system	[redacted]
3.4.4	Test conditions	[redacted]
3.4.5	Duration of the test	[redacted]
3.4.6	Test parameter	[redacted]
3.4.7	Sampling	[redacted]
3.4.8	Monitoring of TS concentration	[redacted]
3.4.9	Statistics	[redacted]
	4 RESULTS	
4.1	**Limit Test**	[redacted]
4.1.1	Concentration	[redacted]
4.1.2	Number/ percentage of animals showing adverse effects	[redacted]
4.1.3	Nature of adverse effects	[redacted]
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	[redacted]

Section A7.4.1.1/02 **Acute toxicity to fish**

Annex Point IIA, VII.7.1 Sheepshead Minnow (*Cyprinodon variegatus*)

4.2.2	Actual concentrations of test substance	[redacted]
4.2.3	Effect data (Mortality)	[redacted]
4.2.4	Concentration / response curve	[redacted]
4.2.5	Other effects	[redacted]
4.3	**Results of controls**	
4.3.1	Number/ percentage of animals showing adverse effects	[redacted]
4.3.2	Nature of adverse effects	[redacted]
4.4	**Test with reference substance**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test was conducted according to EPA-FIFRA guideline 72-3. It was a flow-through test-system and the Sheepshead minnow (*Cyprinodon variegatus*) was used as test organism.
5.2	**Results and discussion**	[redacted]
5.2.1	NOEC (96 hours)	0.14 mg/L
5.2.2	LC_{50} (96 hours)	0.41 mg/L
5.2.3	LC_{100} (96 hours)	1.1 mg/L

Section A7.4.1.1/02 **Acute toxicity to fish**

Annex Point IIA, VII.7.1 Sheepshead Minnow (*Cyprinodon variegatus*)

5.3	**Conclusion**	[redacted]
5.3.1	Other Conclusions	[redacted]
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	No

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

Section A7.4.1.1/02 Acute toxicity to fish

Annex Point IIA, VII.7.1 Sheepshead Minnow (*Cyprinodon variegatus*)

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

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.1.1/02-3: Test organisms

Criteria	Details
Species/strain	Sheepshead minnow *(Cyprinodon variegatus)*
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Criteria	Details
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.1.1/02-4: Test system

Criteria	Details
Test type	Flow-through
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

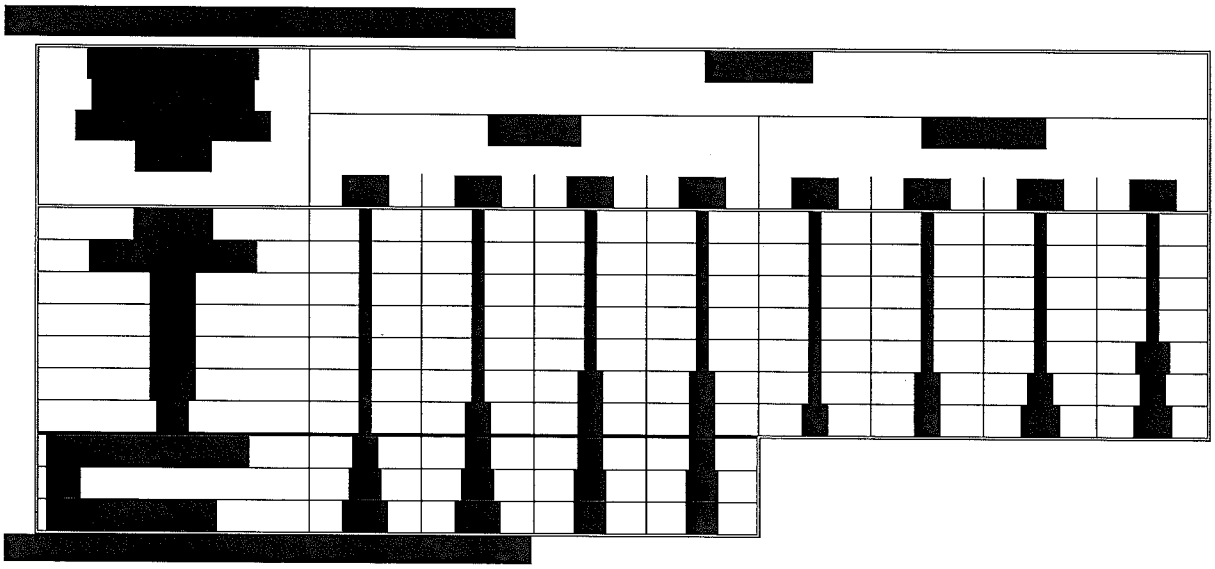


Table A7.4.1.1/02-8: Effect data

	LC_{50}[1] (95 % C.L.)	LC_{100}[1]	NOEC[1]
24 h [mg/L]	> 1.1 (–)	–	0.14
48 h [mg/L]	0.75 (0.64 – 0.88)	–	0.14
72 h [mg/L]	0.49 (0.44 – 0.55)	1.1	0.14
96 h [mg/L]	0.41 (0.38 – 0.46)	1.1	0.14[2]

[1] data are based on mean measured concentrations

NOEC: based on lethargy observed at 0.23 mg ai/L

[redacted]

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]		[redacted]

[redacted]

[redacted]	[redacted]	[redacted]

Section A7.4.1.1/02 Acute toxicity to fish

Annex Point IIA, VII.7.1 Sheepshead Minnow (*Cyprinodon variegatus*)

Official use ouly

1 REFERENCE

1.1	**Reference**	[redacted] (1991): Acute Toxicity to the Sheepshead Minnow (*Cyprinodon variegatus*) under Flow-Through Conditions; [redacted] 12.12.1991;
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, U.S. EPA-FIFRA 72-3 which is comparable to OECD 203
2.2	**GLP**	[redacted]
2.3	**Deviations**	No

3 MATERIAL AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section A2. The purity of the test substance was slightly lower than the specification given in section 2. This does not influence the integrity of the study.
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	[redacted]
3.1.5	Composition of Product	[redacted]
3.1.6	Further relevant properties	[redacted]
3.1.7	Method of analysis	[redacted]

Section A7.4.1.1/02 **Acute toxicity to fish**

Annex Point IIA, VII.7.1 Sheepshead Minnow (*Cyprinodon variegatus*)

3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Testing procedure**	
3.4.1	Dilution water	[redacted]
3.4.2	Test organisms	Sheepshead Minnow [redacted]
3.4.3	Test system	[redacted]
3.4.4	Test conditions	[redacted]
3.4.5	Duration of the test	[redacted]
3.4.6	Test parameter	[redacted]
3.4.7	Sampling	[redacted]
3.4.8	Monitoring of TS concentration	[redacted]
3.4.9	Statistics	[redacted]
	4 RESULTS	
4.1	**Limit Test**	[redacted]
4.1.1	Concentration	[redacted]
4.1.2	Number/ percentage of animals showing adverse effects	[redacted]
4.1.3	Nature of adverse effects	[redacted]
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	[redacted]

Section A7.4.1.1/02 **Acute toxicity to fish**

Annex Point IIA, VII.7.1 Sheepshead Minnow (*Cyprinodon variegatus*)

4.2.2	Actual concentrations of test substance	[redacted]
4.2.3	Effect data (Mortality)	[redacted]
4.2.4	Concentration / response curve	[redacted]
4.2.5	Other effects	[redacted]
4.3	**Results of controls**	
4.3.1	Number/ percentage of animals showing adverse effects	[redacted]
4.3.2	Nature of adverse effects	[redacted]
4.4	**Test with reference substance**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test was conducted according to EPA-FIFRA guideline 72-3. It was a flow-through test-system and the Sheepshead minnow (*Cyprinodon variegatus*) was used as test organism.
5.2	**Results and discussion**	[redacted]
5.2.1	NOEC (96 hours)	0.14 mg/L
5.2.2	LC_{50} (96 hours)	0.41 mg/L
5.2.3	LC_{100} (96 hours)	1.1 mg/L

Section A7.4.1.1/02 **Acute toxicity to fish**

Annex Point IIA, VII.7.1 Sheepshead Minnow (*Cyprinodon variegatus*)

5.3	**Conclusion**	[redacted]
5.3.1	Other Conclusions	[redacted]
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	No

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

Section A7.4.1.1/02 **Acute toxicity to fish**

Annex Point IIA, VII.7.1 Sheepshead Minnow (*Cyprinodon variegatus*)

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

[redacted]

[redacted]

Table A7.4.1.1/02-3: Test organisms

Criteria	Details
Species/strain	Sheepshead minnow *(Cyprinodon variegatus)*
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Criteria	Details
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.1.1/02-4: Test system

Criteria	Details
Test type	Flow-through
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]			
	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

[redacted]	[redacted]							
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]								
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[redacted]								
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[redacted]								
[redacted]								
[redacted]								
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[redacted]								
[redacted]								
[redacted]								

[redacted]

Table A7.4.1.1/02-8: Effect data

	LC_{50}[1] (95 % C.L.)	LC_{100}[1]	NOEC[1]
24 h [mg/L]	> 1.1 (–)	–	0.14
48 h [mg/L]	0.75 (0.64 – 0.88)	–	0.14
72 h [mg/L]	0.49 (0.44 – 0.55)	1.1	0.14
96 h [mg/L]	0.41 (0.38 – 0.46)	1.1	0.14[2]

[1] data are based on mean measured concentrations

NOEC: based on lethargy observed at 0.23 mg ai/L

[redacted]

	[redacted]	[redacted]
[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]		[redacted]

[redacted]

[redacted]	[redacted]	[redacted]

Section A7.4.1.1/03 **Acute toxicity to fish**

Annex Point IIA, VII.7.1 Bluegill Sunfish *(Lepomis macrochirus)*

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (1990): Troysan Polyphase P-100 – Acute toxicity to bluegill sunfish (*Lepomis macrochirus*) under flow-through conditions; Springborn [redacted] 27 June 1990; [redacted]	
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 FIFRA Guideline 72-1, which is comparable to OECD 203	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	No	
		3 MATERIAL AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	As given in section A2. The purity of the test substance was slightly lower than the specification given in section A2. This does not influence the integrity of the study.	
3.1.3	Purity	[redacted]	
3.1.4	Description of test substance	[redacted]	
3.1.5	Composition of Product	[redacted]	
3.1.6	Further relevant properties	[redacted]	
3.1.7	Method of analysis	[redacted]	

Section A7.4.1.1/03 **Acute toxicity to fish**

Annex Point IIA, VII.7.1 Bluegill Sunfish *(Lepomis macrochirus)*

[redacted]

3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Testing procedure**	
3.4.1	Dilution water	[redacted]
3.4.2	Test organisms	Bluegill sunfish (*Lepomis macrochirus*), [redacted]
3.4.3	Test system	[redacted]
3.4.4	Test conditions	[redacted]
3.4.5	Duration of the test	[redacted]
3.4.6	Test parameter	[redacted]
3.4.7	Sampling	[redacted]
3.4.8	Monitoring of TS concentration	[redacted]
3.4.9	Statistics	[redacted]

4 RESULTS

4.1	**Limit Test**	[redacted]
4.1.1	Concentration	[redacted]
4.1.2	Number/ percentage of animals showing adverse effects	[redacted]
4.1.3	Nature of adverse effects	[redacted]

Section A7.4.1.1/03 Acute toxicity to fish

Annex Point IIA, VII.7.1 Bluegill Sunfish *(Lepomis macrochirus)*

4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	[redacted]
4.2.2	Actual concentrations of test substance	[redacted]
4.2.3	Effect data (Mortality)	[redacted]
4.2.4	Concentration / response curve	[redacted]
4.2.5	Other effects	[redacted]
4.3	**Results of controls**	
4.3.1	Number/ percentage of animals showing adverse effects	[redacted]
4.3.2	Nature of adverse effects	[redacted]
4.4	**Test with reference substance**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test was conducted according to FIFRA Guideline 72-1. The test system was flow-through and bluegill sunfish was used as test organism.
5.2	**Results and discussion**	[redacted]
5.2.1	NOEC (96 hours)	140 µg/L
5.2.2	LC_{50} (96 hours)	230 µg/L
5.2.3	LC_{100} (96 hours)	320 µg/L

Section A7.4.1.1/03 **Acute toxicity to fish**

Annex Point IIA, VII.7.1 Bluegill Sunfish *(Lepomis macrochirus)*

5.3	**Conclusion**	[redacted]
5.3.1	Other Conclusions	[redacted]
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	No

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

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.1.1/03-3: Test organisms

Criteria	Details
Species/strain	Bluegill sunfish (*Lepomis macrochirus*)
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.1.1/03-4: Test system

Criteria	Details

Criteria	Details
Test type	Flow-through
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]			
	[redacted]		[redacted]	
	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

[redacted]	[redacted]							
	[redacted]				[redacted]			
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]				
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]				
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]				

Table A7.4.1.1/03-8: Effect data

	48 h [µg/l]	95 % C.L.	96 h [µg/l]	95 % C.L.
NOEC	140	-	140	-
LC_{50}	230	140 - 320	230	140 - 320
LC_{100}	320	-	320	-

effect data are based on measured concentrations

[redacted]

	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[redacted]	[redacted]	[redacted]

[redacted]

Section A7.4.1.1/04 Acute toxicity to fish

Annex Point IIA, VII.7.1 Zebra fish (*Danio rerio,* formerly *Brachydanio rerio)*

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (2001): Preventol MP 100 Acute Fish Toxicity; [redacted] 29.01.2001	
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, EU commission directive 92/69/EEC, C.1 (1992) and OECD 203 (1992)	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	No	
		3 MATERIAL AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	As given in section 2	
3.1.3	Purity	[redacted]	
3.1.4	Description of test substance	[redacted]	
3.1.5	Composition of Product	[redacted]	
3.1.6	Further relevant properties	[redacted]	
3.1.7	Method of analysis	[redacted]	
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]	
3.3	**Reference substance**	[redacted]	

Section A7.4.1.1/04 **Acute toxicity to fish**

Annex Point IIA, VII.7.1 Zebra fish (*Danio rerio,* formerly *Brachydanio rerio)*

3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Testing procedure**	
3.4.1	Dilution water	[redacted]
3.4.2	Test organisms	[redacted]
3.4.3	Test system	[redacted]
3.4.4	Test conditions	[redacted]
3.4.5	Duration of the test	[redacted]
3.4.6	Test parameter	[redacted]
3.4.7	Sampling	[redacted]
3.4.8	Monitoring of TS concentration	[redacted]
3.4.9	Statistics	[redacted]
	4 RESULTS	
4.1	**Limit Test**	[redacted]
4.1.1	Concentration	[redacted]
4.1.2	Number/ percentage of animals showing adverse effects	[redacted]
4.1.3	Nature of adverse effects	[redacted]
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	[redacted]
4.2.2	Actual concentrations of test substance	[redacted]
4.2.3	Effect data (Mortality)	[redacted]

Section A7.4.1.1/04 **Acute toxicity to fish**

Annex Point IIA, VII.7.1 Zebra fish (*Danio rerio,* formerly *Brachydanio rerio)*

4.2.4	Concentration / response curve	[redacted]
4.2.5	Other effects	[redacted]
4.3	**Results of controls**	
4.3.1	Number/ percentage of animals showing adverse effects	[redacted]
4.3.2	Nature of adverse effects	[redacted]
4.4	**Test with reference substance**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test was conducted according to EU commission directive 92/69/EEC, C.1 (1992) and OECD 203 (1992). It was a static test-system and the Zebra fish (*Danio rerio*, formerly *Brachydanio rerio*) was used as test organism.
5.2	**Results and discussion**	[redacted]
5.2.1	NOEC (96 hours)	0.26 mg/L (mean measured)
5.2.2	LC_{50} (96 hours)	0.43 mg/L (mean measured), calculated as mean value between NOEC and LC_{100} due to the steepness of the concentration / response curve)
5.2.3	LC_{100} (96 hours)	0.71 mg/L (mean measured)
5.3	**Conclusion**	[redacted]
5.3.1	Other Conclusions	[redacted]
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	No

Section A7.4.1.1/04 **Acute toxicity to fish**

Annex Point IIA, VII.7.1 Zebra fish (*Danio rerio,* formerly *Brachydanio rerio)*

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

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.1.1/04-3: Test organisms

Criteria	Details
Species/strain	*Danio rereio,* formerly *(Brachydanio rerio* Hamilton-Buchanan)
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.1.1/04-4: Test system

Criteria	Details
Test type	Static

Criteria	Details
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]							
	[redacted]				[redacted]			
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]				
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]				
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]				

[redacted]

Table A7.4.1.1/04-7: Effect data

	48 h [mg/L][1]	95 % C.L.	96 h [mg/L][1]	95 % C.L.
NOEC	0.34	-	0.26	-
LC_{50}	0.49[2]	-	0.43[2]	-
LC_{100}	0.71	-	0.71	-

[1]data are based on mean measured concentrations

[2]estimated as mean between NOEC and LC100 due to the steepness of the dose-response-curve

- = not determined

[redacted]

Section A7.4.1.1/05 Acute toxicity to fish

Annex Point IIA, VII.7.1 Rainbow trout (*Oncorhynchus mykiss*)

[redacted]

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (1994): Acute toxicity of Omacide IPBC to the rainbow trout, *Oncorhynchus mykiss*; [redacted] 11 February 1994; [redacted]
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 FIFRA Guideline 72-1, which is comparable to OECD 203
2.2	**GLP**	[redacted]
2.3	**Deviations**	No

3 MATERIAL AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section 2. The purity of the test substance was slightly lower than the specification given in section 2. This does not influence the integrity of the study.
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	[redacted]
3.1.5	Composition of Product	[redacted]
3.1.6	Further relevant properties	[redacted]

Section A7.4.1.1/05 **Acute toxicity to fish**

Annex Point IIA, VII.7.1 Rainbow trout (*Oncorhynchus mykiss*)

3.1.7	Method of analysis	[redacted]
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Testing procedure**	
3.4.1	Dilution water	[redacted]
3.4.2	Test organisms	Rainbow trout (*Oncorhynchus mykiss*), [redacted]
3.4.3	Test system	[redacted]
3.4.4	Test conditions	[redacted]
3.4.5	Duration of the test	[redacted]
3.4.6	Test parameter	[redacted]
3.4.7	Sampling	[redacted]
3.4.8	Monitoring of TS concentration	[redacted]
3.4.9	Statistics	[redacted]
	4 RESULTS	
4.1	**Limit Test**	[redacted]
4.1.1	Concentration	[redacted]
4.1.2	Number/ percentage of animals showing adverse effects	[redacted]

Section A7.4.1.1/05 **Acute toxicity to fish**

Annex Point IIA, VII.7.1 Rainbow trout (*Oncorhynchus mykiss*)

4.1.3	Nature of adverse effects	[redacted]
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	[redacted]
4.2.2	Actual concentrations of test substance	[redacted]
4.2.3	Effect data (Mortality)	[redacted]
4.2.4	Concentration / response curve	[redacted]
4.2.5	Other effects	[redacted]
4.3	**Results of controls**	
4.3.1	Number/ percentage of animals showing adverse effects	[redacted]
4.3.2	Nature of adverse effects	[redacted]
4.4	**Test with reference substance**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test was conducted according to FIFRA Guideline 72-1. The test system was flow-through and rainbow trout was used as test organism.
5.2	**Results and discussion**	[redacted]
5.2.1	NOEC (96 hours)	46 µg/L
5.2.2	LC_{50} (96 hours)	72 µg/L

Section A7.4.1.1/05 **Acute toxicity to fish**

Annex Point IIA, VII.7.1 Rainbow trout (*Oncorhynchus mykiss*)

5.2.3	LC_{100} (96 hours)	120 µg/L
5.3	**Conclusion**	[redacted] The 96 h-LC_{50} was calculated to be 72 µg/L. The 96 h-NOEC was determined to be 46 µg/L.
5.3.1	Other Conclusions	[redacted]
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	No

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

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.1.1/05-3: Test organisms

Criteria	Details
Species/strain	rainbow trout (*Oncorhynchus mykiss)*
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.1.1/05-4: Test system

Criteria	Details
Test type	Flow-through

Criteria	Details
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]	
	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[redacted]

[redacted]

Table A7.4.1.1/05-8: Effect data

	48 h [µg/l]	95 % C.L.	96 h [µg/l]	95 % C.L.
NOEC	120	-	46	-
LC_{50}	150	120 - 180	72	63 - 83
LC_{100}	180	-	120	-

effect data are based on measured concentrations

[redacted]

[redacted]

Section A7.4.1.1/05b **Acute toxicity to fish**

Annex Point IIA, VII.7.1 Rainbow trout (*Oncorhynchus mykiss*)

[redacted]

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (1990): Troysan Polyphase P-100 – Acute toxicity to rainbow trout (*Oncorhynchus mykiss*) under flow-through conditions; [redacted] 27 June 1990 [redacted]
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. FIFRA Guideline 72-1, which is comparable to OECD 203
2.2	**GLP**	[redacted]
2.3	**Deviations**	No

3 MATERIAL AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section 2. The purity of the test substance was slightly lower than the specification given in section 2. This does not influence the integrity of the study.
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	[redacted]
3.1.5	Composition of Product	[redacted]
3.1.6	Further relevant properties	[redacted]

Section A7.4.1.1/05b **Acute toxicity to fish**

Annex Point IIA, VII.7.1 Rainbow trout (*Oncorhynchus mykiss*)

3.1.7	Method of analysis	[redacted]
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis for reference substance	
3.4	**Testing procedure**	
3.4.1	Dilution water	[redacted]
3.4.2	Test organisms	Rainbow trout (*Oncorhynchus mykiss*), [redacted]
3.4.3	Test system	[redacted]
3.4.4	Test conditions	[redacted]
3.4.5	Duration of the test	[redacted]
3.4.6	Test parameter	[redacted]
3.4.7	Sampling	[redacted]
3.4.8	Monitoring of TS concentration	[redacted]
3.4.9	Statistics	[redacted]
	4 RESULTS	
4.1	**Limit Test**	[redacted]
4.1.1	Concentration	[redacted]

Section A7.4.1.1/05b **Acute toxicity to fish**

Annex Point IIA, VII.7.1 Rainbow trout (*Oncorhynchus mykiss*)

4.1.2	Number/ percentage of animals showing adverse effects	[redacted]
4.1.3	Nature of adverse effects	[redacted]
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	[redacted]
4.2.2	Actual concentrations of test substance	[redacted]
4.2.3	Effect data (Mortality)	[redacted]
4.2.4	Concentration / response curve	[redacted]
4.2.5	Other effects	[redacted]

Section A7.4.1.1/05b **Acute toxicity to fish**

Annex Point IIA, VII.7.1 Rainbow trout (*Oncorhynchus mykiss*)

4.3	**Results of controls**	
4.3.1	Number/ percentage of animals showing adverse effects	[redacted]
4.3.2	Nature of adverse effects	[redacted]
4.4	**Test with reference substance**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test was conducted according to FIFRA Guideline 72-1. The test system was flow-through and rainbow trout was used as test organism.
5.2	**Results and discussion**	[redacted]
5.2.1	NOEC (96 hours)	49 µg/L
5.2.2	LC_{50} (96 hours)	67 µg/L
5.2.3	LC_{100} (96 hours)	120 µg/L
5.3	**Conclusion**	[redacted] The 96 h-LC_{50} was calculated to be 67 µg/L. The 96 h-NOEC was determined to be 49 µg/L.
5.3.1	Other Conclusions	[redacted]
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	No

Section A7.4.1.1/05b **Acute toxicity to fish**

Annex Point IIA, VII.7.1 Rainbow trout (*Oncorhynchus mykiss*)

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

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.1.1/05b-3: Test organisms

Criteria	Details
Species/strain	rainbow trout (*Oncorhynchus mykiss)*
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.1.1/05b-4: Test system

Criteria	Details
Test type	Flow-through
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]		
	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

[redacted]

[redacted]

Table A7.4.1.1/05-8: Effect data

	48 h [µg/l]	95 % C.L.	96 h [µg/l]	95 % C.L.
NOEC		-	49	-
LC_{50}	97	79 – 120	67	49 - 79
LC_{100}		-	120	-

effect data are based on measured concentrations

[redacted]

[redacted]

[redacted]

Section A7.4.1.1/06 **Acute toxicity to fish** (test material is PBC)

Annex Point IIA, VII.7.1 Rainbow trout (*Oncorhynchus mykiss*)

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (1992): (Propargyl Butyl Carbamate) – Acute toxicity to rainbow trout (*Oncorhynchus mykiss*); [redacted] 12 March 1992 [redacted]	
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 FIFRA Guideline 72-1, which is comparable to OECD 203	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	No	
		3 MATERIAL AND METHODS	
3.1	**Test material**	Propargyl Butyl Carbamate [redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	There is no specification for PBC	
3.1.3	Purity	[redacted]	
3.1.4	Description of test substance	[redacted]	
3.1.5	Composition of Product	[redacted]	
3.1.6	Further relevant properties	[redacted]	

Section A7.4.1.1/06 **Acute toxicity to fish** (test material is PBC)

Annex Point IIA, VII.7.1 Rainbow trout (*Oncorhynchus mykiss*)

3.1.7	Method of analysis	[redacted]
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Testing procedure**	
3.4.1	Dilution water	[redacted]
3.4.2	Test organisms	Rainbow trout (*Oncorhynchus mykiss*), [redacted]
3.4.3	Test system	[redacted]
3.4.4	Test conditions	[redacted]
3.4.5	Duration of the test	[redacted]
3.4.6	Test parameter	[redacted]
3.4.7	Sampling	[redacted]
3.4.8	Monitoring of TS concentration	[redacted]
3.4.9	Statistics	[redacted]
	4 RESULTS	
4.1	**Limit Test**	[redacted]
4.1.1	Concentration	[redacted]

Section A7.4.1.1/06 **Acute toxicity to fish** (test material is PBC)
Annex Point IIA, VII.7.1 Rainbow trout (*Oncorhynchus mykiss*)

4.1.2	Number/ percentage of animals showing adverse effects	[redacted]
4.1.3	Nature of adverse effects	[redacted]
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	[redacted]
4.2.2	Actual concentrations of test substance	[redacted]
4.2.3	Effect data (Mortality)	[redacted]
4.2.4	Concentration / response curve	[redacted]
4.2.5	Other effects	[redacted]
4.3	**Results of controls**	
4.3.1	Number/ percentage of animals showing adverse effects	[redacted]
4.3.2	Nature of adverse effects	[redacted]
4.4	**Test with reference substance**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The test was conducted according to FIFRA Guideline 72-1. The test system was flow-through and rainbow trout was used as test organism.

Section A7.4.1.1/06 **Acute toxicity to fish** (test material is PBC)

Annex Point IIA, VII.7.1 Rainbow trout (*Oncorhynchus mykiss*)

5.2	**Results and discussion**	
5.2.1	NOEC (96 hours)	30 mg/L
5.2.2	LC_{50} (96 hours)	85 mg/L
5.2.3	LC_{100} (96 hours)	150 mg/L
5.3	**Conclusion**	[redacted] The 96 h-LC_{50} was calculated to be 85 mg/L. The 96 h-NOEC was determined to be 85 mg/L.
5.3.1	Other Conclusions	[redacted]
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	No

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section A7.4.1.1/06 **Acute toxicity to fish** (test material is PBC)

Annex Point IIA, VII.7.1 Rainbow trout (*Oncorhynchus mykiss*)

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	

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.1.1/06-3: Test organisms

Criteria	Details
Species/strain	rainbow trout (*Oncorhynchus mykiss)*
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.1.1/06-4: Test system

Criteria	Details
Test type	Flow-through
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]			
	[redacted]		[redacted]	
	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

[redacted]	[redacted]							
	[redacted]				[redacted]			
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]				
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]				
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]				

Table A7.4.1.1/06-8: Effect data

	48 h [mg/l]	95 % C.L.	96 h [mg/l]	95 % C.L.
NOEC	30	-	30	-
LC_{50}	95	82 - 110	85	74 - 97
LC_{100}	-	-	150	-

Effect data are based on measured concentrations

[redacted]

Section A7.4.1.2/01 Acute toxicity to invertebrates

Annex Point IIA, VII.7.2 *Daphnia magna*

[redacted]

Official use only

1 REFERENCE

1.1	**Reference**	Boeri, R.L., Magazu, J.P., Ward, T.J. (1994): Acute Toxicity of Omacide® IPBC to the Daphnid, *Daphnia magna*; T.R. Wilbury Laboratories, Marblehead, Massachusetts, USA; Study No.: 292-OL; 11.02.1994; Doc. No. 822-002; (unpublished)
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, U.S. EPA-FIFRA 72-2, which is comparable to OECD 202
2.2	**GLP**	[redacted]
2.3	**Deviations**	No

3 MATERIAL AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section A2. The purity of the test substance was slightly lower than the specification given in section A2. This does not influence the integrity of the study.
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	[redacted]
3.1.5	Composition of Product	[redacted]
3.1.6	Further relevant properties	[redacted]

Section A7.4.1.2/01 Acute toxicity to invertebrates

Annex Point IIA, VII.7.2 *Daphnia magna*

3.1.7	Method of analysis	[redacted]
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Testing procedure**	
3.4.1	Dilution water	[redacted]
3.4.2	Test organisms	*Daphnia magna* [redacted]
3.4.3	Test system	[redacted]
3.4.4	Test conditions	[redacted]
3.4.5	Duration of the test	[redacted]
3.4.6	Test parameter	[redacted]
3.4.7	Sampling	[redacted]
3.4.8	Monitoring of TS concentration	[redacted]
3.4.9	Statistics	[redacted]
	4 RESULTS	
4.1	**Limit Test**	[redacted]
4.1.1	Concentration	[redacted]
4.1.2	Number/ percentage of animals showing adverse effects	[redacted]
4.1.3	Nature of adverse effects	[redacted]

Section A7.4.1.2/01 **Acute toxicity to invertebrates**

Annex Point IIA, VII.7.2 *Daphnia magna*

4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	[redacted]
4.2.2	Actual concentrations of test substance	[redacted]
4.2.3	Effect data (Mortality)	[redacted]
4.2.4	Concentration / response curve	[redacted]
4.2.5	Other effects	[redacted]
4.3	**Results of controls**	
4.3.1	Number/ percentage of animals showing adverse effects	[redacted]
4.3.2	Nature of adverse effects	[redacted]
4.4	**Test with reference substance**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test was conducted according to EPA-FIFRA guideline 72-2. It was a flow-through test-system and *Daphnia magna* was used as test organism.
5.2	**Results and discussion**	[redacted]

Section A7.4.1.2/01 Acute toxicity to invertebrates

Annex Point IIA, VII.7.2 *Daphnia magna*

5.2.1	EC_0	0.076 mg/L (48 hours)
5.2.2	EC_{50}	0.16 mg/L (48 hours)
5.2.3	EC_{100}	0.28 mg/L (48 hours)
5.3	**Conclusion**	[redacted] The EC_{50} was calculated to be 0.16 mg ai/L, based on mean measured values. The NOEC was determined to be 0.076 mg ai/L (mean measured), based on sublethal effects at the next higher test concentration.
5.3.1	Other Conclusions	[redacted]
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	No

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

Section A7.4.1.2/01 Acute toxicity to invertebrates

Annex Point IIA, VII.7.2 *Daphnia magna*

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

[redacted]

[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	

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[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	

Table A7.4.1.2/01-3: Test organisms

Criteria	Details
Strain	*Daphnia magna*
[redacted]	[redacted]
[redacted]	[redacted]

Criteria	Details
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Table A7.4.1.2/01-8: Effect data

	EC_{50}[1]	95 % C.I.	EC_0[1]	EC_{100}[1]
24 h [mg/L]	0.24	0.20 to 0.28	0.076	0.52
48 h [mg/L]	0.16	0.14 to 0.17	0.076	0.28

[1]data are based on measured concentrations

[redacted]

	[redacted]	[redacted]
[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]	[redacted]	

[redacted]	[redacted]	[redacted]

Section A7.4.1.2/02 **Acute toxicity to invertebrates** (test material is PBC)

Annex Point IIA, VII.7.2 *Daphnia magna*

			Official use only
		1 REFERENCE	
1.1	**Reference**	Putt, A.E. (1992): (Propargyl Butyl Carbamate) Acute Toxicity to Daphnids (*Daphnia magna*) Under Flow-Through Conditions; Springborn Laboratories Inc., Wareham, Massachusetts, USA; Study No.: 12166.0991.6109.115; Lab.-Report No.: 92-2-4122; 27.02.1992; Doc. No. 822-004; (unpublished)	
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, U.S. EPA-FIFRA 72-2, which is comparable to OECD 202	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	No	
		3 MATERIAL AND METHODS	
3.1	**Test material**	Propargyl Butyl Carbamate	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	There is no specification for PBC	
3.1.3	Purity	[redacted]	
3.1.4	Description of test substance	[redacted]	
3.1.5	Composition of Product	[redacted]	
3.1.6	Further relevant properties	[redacted]	
3.1.7	Method of analysis	[redacted]	

Section A7.4.1.2/02 **Acute toxicity to invertebrates** (test material is PBC)

Annex Point IIA, VII.7.2 *Daphnia magna*

3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Testing procedure**	
3.4.1	Dilution water	[redacted]
3.4.2	Test organisms	*Daphnia magna* [redacted]
3.4.3	Test system	[redacted]
3.4.4	Test conditions	[redacted]
3.4.5	Duration of the test	[redacted]
3.4.6	Test parameter	[redacted]
3.4.7	Sampling	[redacted]
3.4.8	Monitoring of TS concentration	[redacted]
3.4.9	Statistics	[redacted]

4 RESULTS

4.1	**Limit Test**	[redacted]
4.1.1	Concentration	[redacted]
4.1.2	Number/ percentage of animals showing adverse effects	[redacted]
4.1.3	Nature of adverse effects	[redacted]
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	[redacted]

Section A7.4.1.2/02 **Acute toxicity to invertebrates** (test material is PBC)
Annex Point IIA, VII.7.2 *Daphnia magna*

4.2.2	Actual concentrations of test substance	[redacted]
4.2.3	Effect data (Mortality)	[redacted]
4.2.4	Concentration / response curve	[redacted]
4.2.5	Other effects	[redacted]
4.3	**Results of controls**	
4.3.1	Number/ percentage of animals showing adverse effects	[redacted]
4.3.2	Nature of adverse effects	[redacted]
4.4	**Test with reference substance**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test was conducted according to EPA-FIFRA guideline 72-2. It was a flow-through test-system and *Daphnia magna* was used as test organism.
5.2	**Results and discussion**	[redacted]
5.2.1	EC_0	17 mg/L (48 hours), based on mean measured values

Section A7.4.1.2/02 **Acute toxicity to invertebrates** (test material is PBC)

Annex Point IIA, VII.7.2 *Daphnia magna*

5.2.2	EC_{50}	60 mg/L (48 hours), based on mean measured values
5.2.3	EC_{100}	150 mg/L (48 hours), based on mean measured values
5.3	**Conclusion**	[redacted]
5.3.1	Other Conclusions	[redacted]
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	No

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	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	

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.1.2/02-3: Test organisms

Criteria	Details
Strain	*Daphnia magna*
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]					
	[redacted]		[redacted]		[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

[redacted]	[redacted]				[redacted]	[redacted]	[redacted]
	[redacted]		[redacted]				
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

[redacted]

[redacted]

Table A7.4.1.2/02-8: Effect data

	EC_{50}[1]	95 % C.L.	EC_0[1]	EC_{100}[1]
24 h [mg/L]	84	48 – 150	17	150
48 h [mg/L]	60	51 – 71	17	150

[1] data are based on measured concentrations

[redacted]

	[redacted]	[redacted]
[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]		[redacted]

[redacted]

[redacted]	[redacted]	[redacted]

Section A7.4.1.3/01 Growth inhibition test on algae

Annex Point IIA, VII.7.3 *Scenedesmus subspicatus*

[redacted]

Official use only

1 REFERENCE

1.1	**Reference**	Peither, A. (2001): Toxicity of Polyphase P-100 to *Scenedesmus subspicatus* in a 72-hour Algal Growth Inhibition Test; RCC Ltd, Itingen, Switzerland; Study No.: 790413; 27.06.2001; Doc. No. 823-003; (unpublished)
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, OECD No. 201 (1984) and European Commission Directive 92/69/EEC, C.3 (1992)
2.2	**GLP**	[redacted]
2.3	**Deviations**	No

3 MATERIAL AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in Section A2.
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	[redacted]
3.1.5	Composition of Product	[redacted]
3.1.6	Further relevant properties	[redacted]

Section A7.4.1.3/01 **Growth inhibition test on algae**

Annex Point IIA, VII.7.3 ***Scenedesmus subspicatus***

3.1.7	Method of analysis	[redacted]
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Testing procedure**	
3.4.1	Culture medium	[redacted]
3.4.2	Test organisms	*Scenedesmus subspicatus*, [redacted]
3.4.3	Test system	[redacted]
3.4.4	Test conditions	[redacted]
3.4.5	Duration of the test	[redacted]
3.4.6	Test parameter	[redacted]
3.4.7	Sampling	[redacted]
3.4.8	Monitoring of TS concentration	[redacted]
3.4.9	Statistics	[redacted]

4 RESULTS

4.1	**Limit Test**	[redacted]
4.1.1	Concentration	[redacted]
4.1.2	Nature of adverse effects	[redacted]
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	[redacted]

Section A7.4.1.3/01 **Growth inhibition test on algae**

Annex Point IIA, VII.7.3 ***Scenedesmus subspicatus***

4.2.2	Actual concentrations of test substance	[redacted]
4.2.3	Growth curves	[redacted]
4.2.4	Concentration / response curve	[redacted]
4.2.5	Cell concentration data	[redacted]
4.2.6	Effect data (cell multiplication inhibition)	[redacted]
4.2.7	Other observed effects	[redacted]
4.3	**Results of controls**	
4.3.1	Nature of adverse effects	[redacted]
4.4	**Test with reference substance**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test was conducted according to OECD guideline 201 and EU Commission Directive 92/69/EEC, C.3. It was a static test-system and *Scenedesmus subspicatus* was used as test organism.
5.2	**Results and discussion**	[redacted]
5.2.1	NOEC (biomass)	4.6 µg/L
5.2.2	NOEC (growth rate)	4.6 µg/L
5.2.3	E_bC_{50}	22 µg/L
5.2.4	E_rC_{50}	53 µg/L

Section A7.4.1.3/01 Growth inhibition test on algae

Annex Point IIA, VII.7.3 *Scenedesmus subspicatus*

5.3	**Conclusion**	[redacted] Based on the results the EC_{50} (biomass) was calculated to be 22 µg/L, the EC_{50} (growth rate) was determined to be 53 µg/L. The NOEC for biomass as well as for growth rate was determined to be 4.6 µg/L.
5.3.1	Other Conclusions	[redacted]
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	No

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section A7.4.1.3/01 Growth inhibition test on algae

Annex Point IIA, VII.7.3 ***Scenedesmus subspicatus***

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	

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.1.3/01-3: Test organism

Criteria	Details
Species	*Scenedesmus subspicatus* CHODAT
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Table A7.4.1.3/01-8: Effect data

	EC_{50}[1]	95 % C.L.	NOEC[1]
24 h [µg/L]	ND	ND	4.6
48 h [µg/L]	ND	ND	4.6
72 h [µg/L] (biomass)	22	17 – 33	4.6
72 h [µg/L] (growth rate)	53	32 – ND	4.6

[1] data are based on nominal concentrations

ND = not determined

[redacted]

[redacted]

[redacted]

Section A7.4.1.3/02 Growth inhibition test on algae

Annex Point IIA, VII.7.3 *Selenastrum capricornutum*

			Official use only
		1 REFERENCE	
1.1	**Reference**	Boeri, R.L., Magazu, J.P., Ward, T.J. (1994): Growth and Reproduction Test with Omacide® IPBC and the Freshwater Alga, *Selenastrum capricornutum*; T.R. Wilbury Laboratories, Marblehead, Massachusetts, USA; Study No.: 295-OL; 07.02.1994; Doc. No. 823-001; (unpublished): No	
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, U.S. EPA-FIFRA 122-2, which is comparable to OECD 201	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	No	
		3 MATERIAL AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	As given in Section A2. The purity of the test substance was slightly lower than the specification given in section 2. This does not influence the integrity of the study.	
3.1.3	Purity	[redacted]	
3.1.4	Description of test substance	[redacted]	
3.1.5	Composition of Product	[redacted]	
3.1.6	Further relevant properties	[redacted]	
3.1.7	Method of analysis	[redacted]	

Section A7.4.1.3/02 Growth inhibition test on algae

Annex Point IIA, VII.7.3 *Selenastrum capricornutum*

3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Testing procedure**	
3.4.1	Culture medium	[redacted]
3.4.2	Test organisms	[redacted]
3.4.3	Test system	[redacted]
3.4.4	Test conditions	[redacted]
3.4.5	Duration of the test	[redacted]
3.4.6	Test parameter	[redacted]
3.4.7	Sampling	[redacted]
3.4.8	Monitoring of TS concentration	[redacted]
3.4.9	Statistics	[redacted]
	4 RESULTS	
4.1	**Limit Test**	[redacted]
4.1.1	Concentration	[redacted]
4.1.2	Nature of adverse effects	[redacted]
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	[redacted]

Section A7.4.1.3/02 **Growth inhibition test on algae**

Annex Point IIA, VII.7.3 ***Selenastrum capricornutum***

4.2.2	Actual concentrations of test substance	[redacted]
4.2.3	Growth curves	[redacted]
4.2.4	Concentration / response curve	[redacted]
4.2.5	Cell concentration data	[redacted]
4.2.6	Effect data (cell multiplication inhibition)	[redacted]
4.2.7	Other observed effects	[redacted]
4.3	**Results of controls**	
4.3.1	Nature of adverse effects	[redacted]
4.4	**Test with reference substance**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test was conducted according to EPA-FIFRA guideline 122-2. It was a static test-system and *Selenastrum capricornutum* was used as test organism.
5.2	**Results and discussion**	[redacted]
5.2.1	NOEC	< 0.089 mg/L (given as 120 hour value, based on cell number)
5.2.2	EC_{50}	0.10 mg/L (given as 120 hour value, based on cell number)

Section A7.4.1.3/02 Growth inhibition test on algae

Annex Point IIA, VII.7.3 *Selenastrum capricornutum*

5.3	**Conclusion**	[redacted] Based on the results, the EC_{50} was calculated to be 0.10 mg/L, based on cell number and initial measured values. The NOEC was determined to be < 0.089, the lowest concentration tested, also based on initial measured values.
5.3.1	Other Conclusions	[redacted]
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	No

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section A7.4.1.3/02 Growth inhibition test on algae

Annex Point IIA, VII.7.3 ***Selenastrum capricornutum***

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	

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.1.3/02-2: Test organisms

Criteria	Details
Species	**Selenastrum capricornutum**
Strain	UTEX 1648
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]			
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

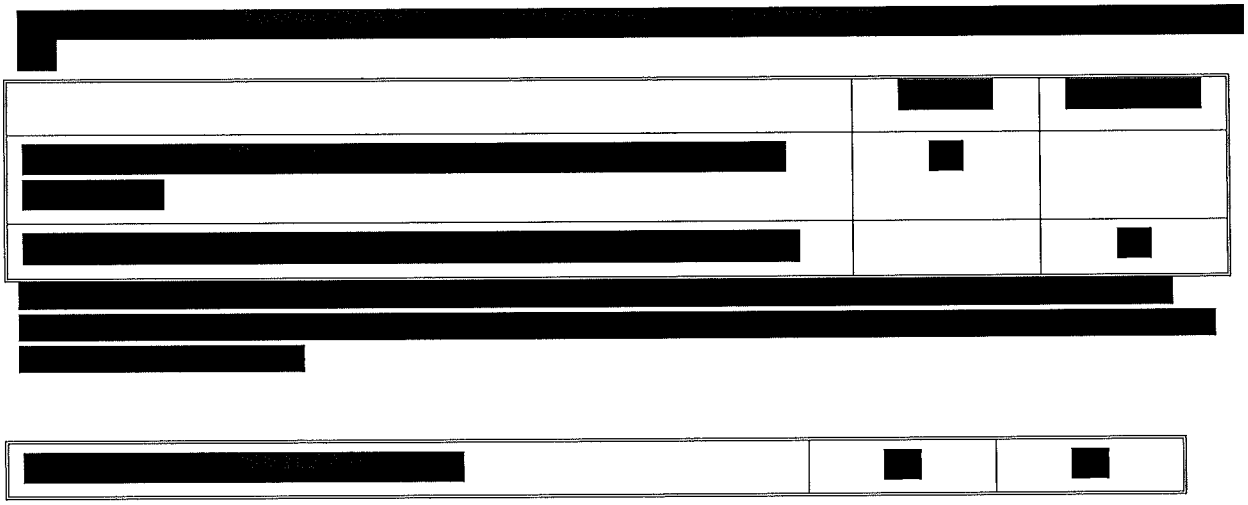
Table A7.4.1.3/02-7: Effect data

	EC_{50}[1]	95 % C.L.	NOEC[1]
24 h [mg/L]	0.15	0.089 – 0.36	ND
48 h [mg/L]	0.10	0.089 – 0.16	ND
72 h [mg/L]	0.095	0.089 – 0.16	ND
96 h [mg/L]	> 0.089	—	ND
120 h [mg/L]	0.10	0.089 – 0.16	< 0.089

[1] data are based on initial measured concentrations

ND = not determined

— = not given



Section A7.4.1.3/03 Growth inhibition test on algae (test material is PBC)

Annex Point IIA, VII.7.3 ***Selenastrum capricornutum***

Official use only

1 REFERENCE

1.1	**Reference**	Ward, T.J., Magazu, J.P., Boeri, R.L. (1997): Growth and Reproduction Toxicity Test with Propargyl Butyl Carbamate and the Freshwater Alga, *Selenastrum capricornutum*; T.R. Wilbury Laboratories, Marblehead, Massachusetts, USA; Study No.: 1115-TR; 05.07.1997; Doc. No. 823-004; (unpublished)
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, TSCA 797.1050, which is comparable to OECD 201
2.2	**GLP**	[redacted]
2.3	**Deviations**	Yes, a five times higher concentration of vehicle was used. This will have no impact on the outcome of the study

3 MATERIAL AND METHODS

3.1	**Test material**	Propargyl Butyl Carbamate
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	There is no specification for PBC
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	[redacted]
3.1.5	Composition of Product	[redacted]
3.1.6	Further relevant properties	[redacted]
3.1.7	Method of analysis	[redacted]
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]

Section A7.4.1.3/03 **Growth inhibition test on algae** (test material is PBC)

Annex Point IIA, VII.7.3 ***Selenastrum capricornutum***

3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Testing procedure**	
3.4.1	Culture medium	[redacted]
3.4.2	Test organisms	*Selenastrum capricornutum.* [redacted]
3.4.3	Test system	[redacted]
3.4.4	Test conditions	[redacted]
3.4.5	Duration of the test	[redacted]
3.4.6	Test parameter	[redacted]
3.4.7	Sampling	[redacted]
3.4.8	Monitoring of TS concentration	[redacted]
3.4.9	Statistics	[redacted]

4 RESULTS

4.1	**Limit Test**	[redacted]
4.1.1	Concentration	[redacted]
4.1.2	Nature of adverse effects	[redacted]
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	[redacted]
4.2.2	Actual concentrations of test substance	[redacted]
4.2.3	Growth curves	[redacted]
4.2.4	Concentration / response curve	[redacted]

Section A7.4.1.3/03 **Growth inhibition test on algae** (test material is PBC)

Annex Point IIA, VII.7.3 ***Selenastrum capricornutum***

4.2.5	Cell concentration data	[redacted]
4.2.6	Effect data (cell multiplication inhibition)	[redacted]
4.2.7	Other observed effects	[redacted]
4.3	**Results of controls**	
4.3.1	Nature of adverse effects	[redacted]
4.4	**Test with reference substance**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test was conducted according to TSCA 797.1050. It was a static test-system and *Selenastrum capricornutum* was used as test organism.
5.2	**Results and discussion**	[redacted]
5.2.1	NOEC (cell numbers)	21.2 mg/L
5.2.2	NOEC (biomass)	21.2 mg/L
5.2.3	EC_{50} (cell numbers)	> 41.3 mg/L
5.2.4	EC_{50} (biomass)	> 41.3 mg/L
5.3	**Conclusion**	[redacted]
5.3.1	Other Conclusions	[redacted]
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	No

Section A7.4.1.3/03 **Growth inhibition test on algae** (test material is PBC)

Annex Point IIA, VII.7.3 ***Selenastrum capricornutum***

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

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.1.3/03-2: Test organisms

Criteria	Details
Species	*Selenastrum capricornutum*
Strain	UTEX 1648
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]

[redacted]

[redacted]

Table A7.4.1.3/03-7: Effect data

	Based on cell numbers			Based on growth rate		
	EC_{50}[1] [mg/L]	95 % C.L. [mg/L]	NOEC[1] [mg/L]	EC_{50}[1] [mg/L]	95 % C.L. [mg/L]	NOEC[1] [mg/L]
24 h	> 41.3	< 2.27 to > 41.3	ND	25.7	< 2.27 to > 41.3	ND
48 h	> 41.3	> 41.3	ND	> 41.3	< 10.2 to > 41.3	ND
72 h	> 41.3	30.4 to > 41.3	ND	> 41.3	< 38.9 to > 41.3	ND
96 h	> 41.3	40.6 to > 41.3	21.2	> 41.3	> 41.3	21.2

[1] data are based on mean measured concentrations

ND = not determined

[redacted]

Section A7.4.1.4/01 Inhibition to microbial activity (aquatic)

Annex Point IIA, VII.7.4 *Activated sludge*

[redacted]

Official use only

1 REFERENCE

1.1	**Reference**	Müller, Caspers (2000): Preventol MP 100 – Toxicity to bacteria; Bayer AG, Institut of Environmental Analysis, Leverkusen, Germany; Lab.-Report No.: not specified; Study No.: 1025 A/00 B; 20 October 2000; Doc. No 842-001; (unpublished)
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. EU Commission Directive 88/302/EEC, Part C11
2.2	**GLP**	[redacted]
2.3	**Deviations**	No

3 MATERIAL AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section A2.
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	[redacted]
3.1.5	Composition of Product	[redacted]
3.1.6	Further relevant properties	[redacted]
3.1.7	Method of analysis	[redacted]

Section A7.4.1.4/01 Inhibition to microbial activity (aquatic)

Annex Point IIA, VII.7.4 *Activated sludge*

3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Testing procedure**	
3.4.1	Culture medium	[redacted]
3.4.2	Inoculum / test organism	[redacted]
3.4.3	Test system	[redacted]
3.4.4	Test conditions	[redacted]
3.4.5	Duration of the test	[redacted]
3.4.6	Test parameter	[redacted]
3.4.7	Analytical parameter	[redacted]
3.4.8	Sampling	[redacted]
3.4.9	Monitoring of TS concentration	[redacted]
3.4.10	Controls	[redacted]
3.4.11	Statistics	[redacted]
	4 RESULTS	
4.1	**Preliminary test**	[redacted]
4.1.1	Concentration	[redacted]
4.1.2	Effect data	[redacted]
4.2	**Results test substance**	

Section A7.4.1.4/01 **Inhibition to microbial activity (aquatic)**

Annex Point IIA, VII.7.4 ***Activated sludge***

4.2.1	Initial concentrations of test substance	[redacted]
4.2.2	Actual concentrations of test substance	[redacted]
4.2.3	Growth curves	[redacted]
4.2.4	Cell concentration data	[redacted]
4.2.5	Concentration/ response curve	[redacted]
4.2.6	Effect data	[redacted]
4.2.7	Other observed effects	[redacted]
4.3	**Results of controls**	[redacted]
4.4	**Test with reference substance**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test was conducted according to EU Commission Directive 88/302/EEC, Part C11. The test organisms were activated sludge from an aeration tank of a waste water treatment plant treating predominantly domestic sewage.
5.2	**Results and discussion**	
5.2.1	EC_{20}	Data not provided.
5.2.2	EC_{50}	44 mg/L
5.2.3	EC_{80}	Data not provided.
5.3	**Conclusion**	[redacted]
5.3.1	Other Conclusions	[redacted]

Section A7.4.1.4/01 Inhibition to microbial activity (aquatic)

Annex Point IIA, VII.7.4 ***Activated sludge***

5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	The pH was only reported for the start of the test and not for the end of the test. However, this deviation from guideline is not considered to have impact on the validity of the results:

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

COMMENTS FROM ...

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

Section A7.4.1.4/01 Inhibition to microbial activity (aquatic)

Annex Point IIA, VII.7.4 ***Activated sludge***

Remarks

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.1.4/01-2: Inoculum / Test organism

Criteria	Details
Nature	activated sludge
Species	mixed population of aquatic microorganisms
Strain	Details are not provided.
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]	

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Section A7.4.1.4/02 Inhibition to microbial activity (aquatic)

Annex Point IIA, VII.7.4 ***Pseudomonas putida***

			Official use only
		1 REFERENCE	
1.1	**Reference**	Mead, C. (2002): IPBC: Acute toxicity to bacteria (*Pseudomonas putida*); Safepharm Laboratories Limited, Derby, U.K.; Study No.: 1597/006; 06 March 2002; Doc. No. 842-003; (unpublished)	
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, The method followed that described in the German Water Hazard Classification Scheme (Bewertung Wassergefährdender Stoffe, LTWS-Nr. 10) and ISO 10712 "Determination of the inhibitory effect of water constituents on bacteria (*Pseudomonas* cell multiplication inhibition test)"	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	No	
		3 MATERIAL AND METHODS	
3.1	**Test material**		
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	Not indicated	
3.1.3	Purity	[redacted]	
3.1.4	Description of test substance	[redacted]	
3.1.5	Composition of Product	[redacted]	
3.1.6	Further relevant properties	[redacted]	
3.1.7	Method of analysis	[redacted]	
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]	

Section A7.4.1.4/02 Inhibition to microbial activity (aquatic)

Annex Point IIA, VII.7.4 ***Pseudomonas putida***

3.3	**Reference substance**	
3.3.1	Method of analysis for reference substance	
3.4	**Testing procedure**	
3.4.1	Culture medium	
3.4.2	Inoculum / test organism	
3.4.3	Test system	
3.4.4	Test conditions	
3.4.5	Duration of the test	
3.4.6	Test parameter	
3.4.7	Analytical parameter	
3.4.8	Sampling	
3.4.9	Monitoring of TS concentration	
3.4.10	Controls	

Section A7.4.1.4/02 Inhibition to microbial activity (aquatic)

Annex Point IIA, VII.7.4 ***Pseudomonas putida***

3.4.11	Statistics	[redacted]
		4 RESULTS
4.1	**Preliminary test**	[redacted]
4.1.1	Concentration	[redacted]
4.1.2	Effect data	[redacted]
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	[redacted]
4.2.2	Actual concentrations of test substance	[redacted]
4.2.3	Growth curves	[redacted]
4.2.4	Cell concentration data	[redacted]
4.2.5	Concentration/ response curve	[redacted]
4.2.6	Effect data	[redacted]
4.2.7	Other observed effects	[redacted]
4.3	**Results of controls**	[redacted]
4.4	**Test with reference substance**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

Section A7.4.1.4/02 Inhibition to microbial activity (aquatic)

Annex Point IIA, VII.7.4 ***Pseudomonas putida***

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The test was conducted according to ISO 10712 "Determination of the inhibitory effect of water constituents on bacteria (*Pseudomonas* cell multiplication inhibition test)". [redacted]

5.2 Results and discussion

5.2.1 EC_{20} Data not provided. EC_{10}: 1.8 mg/L

5.2.2 EC_{50} 91 mg/L

5.2.3 EC_{80} Data not provided.

5.3 Conclusion

[redacted]

The 16-hours EC_{50} was calculated to be 91 mg/L.

5.3.1 Other Conclusions [redacted]

5.3.2 Reliability [redacted]

5.3.3 Deficiencies No

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date [redacted]

Materials and Methods [redacted]

Results and discussion [redacted]

Conclusion [redacted]

Reliability [redacted]

Acceptability [redacted]

Section A7.4.1.4/02 Inhibition to microbial activity (aquatic)

Annex Point IIA, VII.7.4 ***Pseudomonas putida***

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	

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.1.4/02-2: Inoculum / Test organism

Criteria	Details
Nature	Bacteria (gram-negative)
Species	*Pseudomonas putida*
Strain	NCIMB 8248
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]		[redacted]
[redacted]		[redacted]	[redacted]
[redacted]		[redacted]	[redacted]
[redacted]		[redacted]	[redacted]
[redacted]		[redacted]	[redacted]
[redacted]		[redacted]	[redacted]
[redacted]		[redacted]	[redacted]
[redacted]		[redacted]	[redacted]
[redacted]		[redacted]	[redacted]
[redacted]		[redacted]	[redacted]
[redacted]		[redacted]	[redacted]
[redacted]		[redacted]	[redacted]

Section A7.4.2 Annex Point IIA, VII.7.5	Bioconcentration in aquatic organisms
	JUSTIFICATION FOR NON-SUBMISSION OF DATA Official use only
	Scientifically unjustified
Detailed justification:	[redacted]According to the TNsG on data requirements, the intrinsic potential for bio-concentration in aquatic organisms should be estimated on the basis of physical and chemical properties. The most important indicator of the bio-accumulation potential is the octanol/water partition coefficient. According to the TGD on Risk Assessment, the bio-concentration potential of an active substance should be determined, when the log K_{ow} is greater or equal to 3. [redacted] From the above arguments, it is not necessary to perform a specific study on the bio-concentration potential of IPBC or its degradation product PBC.
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*

Section A7.4.2 Annex Point IIA, VII.7.5	Bioconcentration in aquatic organisms
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 A7.4.3.2/01 Effects on reproduction and growth rate of fish

Annex Point IIIA, XIII.2.2

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (1992): Troysan Polyphase P-100 – Toxicity to fathead minnow (*Pimephales promelas*) embryos and larvae; [redacted] 22 June 1992
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**	[redacted] FIFRA Guideline 72-4, which is comparable to OECD 210
2.2	**GLP**	[redacted]
2.3	**Deviations**	No

3 MATERIAL AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section A2. The purity of the test substance was slightly lower than the specification given in section A2. This does not influence the integrity of the study.
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	[redacted]
3.1.5	Composition of Product	[redacted]
3.1.6	Further relevant properties	[redacted]

Section A7.4.3.2/01 Effects on reproduction and growth rate of fish

Annex Point IIIA, XIII.2.2

3.1.7	Method of analysis	[redacted]
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Testing procedure**	
3.4.1	Dilution water	[redacted]
3.4.2	Test organisms	Fathead minnow (*Pimephales promelas*), [redacted]
3.4.3	Handling of embryos and larvae (OECD 210/212)	[redacted]
3.4.4	Test system	[redacted]
3.4.5	Test conditions	[redacted]
3.4.6	Duration of the test	[redacted]
3.4.7	Test parameter(s)	[redacted]

Section A7.4.3.2/01 Effects on reproduction and growth rate of fish

Annex Point IIIA, XIII.2.2

3.4.8	Examination / Sampling	[redacted]
3.4.9	Monitoring of TS concentration	[redacted]
3.4.10	Statistics	[redacted]

4 RESULTS

4.1	**Range finding test**	[redacted]
4.1.1	Concentrations	[redacted]
4.1.2	Number/ percentage of animals showing adverse effects	[redacted]
4.1.3	Nature of adverse effects	[redacted]
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	[redacted]
4.2.2	Actual concentrations of test substance	[redacted]

Section A7.4.3.2/01 Effects on reproduction and growth rate of fish

Annex Point IIIA, XIII.2.2

4.2.3	Effect data	[redacted]
4.2.4	Concentration / response curve	[redacted]
4.2.5	Other effects	[redacted]
4.3	**Results of controls**	
4.3.1	Number/ percentage of animals showing adverse effects	[redacted]
4.3.2	Nature of adverse effects	[redacted]
4.4	**Test with reference substance**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test was conducted according to FIFRA Guideline 72-4. The test system was flow-through and fathead minnow was used as test organism.
5.2	**Results and discussion**	[redacted]
5.2.1	NOEC	8.4 µg/L (35 days, parameter: larval growth (length and weight)
5.2.2	LOEC	19 µg/L (35 days, parameter: larval growth (length and weight)

Section A7.4.3.2/01 Effects on reproduction and growth rate of fish

Annex Point IIIA, XIII.2.2

5.3	**Conclusion**	[redacted] The 35 d-NOEC was determined to be 8.4 µg/L based on larval growth (length and weight).
5.3.1	Other Conclusions	[redacted]
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	No

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	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	

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.3.2/01-3: Test organisms

Criteria	Details
Species/strain	Fathead minnow (*Pimephales promelas*)
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.3.2/01-4: Test system

Criteria	Details
Test type	Flow-through
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]							
[redacted]	[redacted]							
[redacted]	[redacted]							
[redacted]	[redacted]							
[redacted]	[redacted]							
[redacted]	[redacted]							
[redacted]	[redacted]							
[redacted]	[redacted]							
[redacted]	[redacted]							
[redacted]	[redacted]							
[redacted]	[redacted]							
[redacted]	[redacted]							
[redacted]	[redacted]							
[redacted]	[redacted]							

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table A7.4.3.2/01-7: NOEC and LOEC values

Endpoint	NOEC [µg/L]	LOEC [µg/L]
Survival of organisms at hatch	27	57
Larval survival	57	> 57
Total larval length	8.4	19
Total larval weight	8.4	19

[redacted]

Section A7.4.3.4/01 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**	Ward, G.S. (1991): Troysan Polyphase P100: Chronic Toxicity to the Water Flea *Daphnia magna* under Flow-Through Test Conditions, Toxicon Environmental Sciences, Jupiter, Florida, USA, Study No.: J9009031b, 08.02.1991; Doc. No. 827-001; (unpublished)
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, U.S. EPA-FIFRA 72-4 (1982) and OECD 202 (1984)
2.2	**GLP**	[redacted]
2.3	**Deviations**	No

3 MATERIAL AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section A2. The purity of the test substance was slightly lower than the specification given in section 2. This does not influence the integrity of the study.
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	[redacted]
3.1.5	Composition of Product	[redacted]
3.1.6	Further relevant properties	[redacted]
3.1.7	Method of analysis	[redacted]

Section A7.4.3.4/01 Effects on reproduction and growth rate with an invertebrate species

Annex Point IIIA, XIII.2.4 *Daphnia magna*

3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Testing procedure**	
3.4.1	Dilution water	[redacted]
3.4.2	Test organisms	*Daphnia magna*, [redacted]
3.4.3	Handling of offspring	[redacted]
3.4.4	Test system	[redacted]
3.4.5	Test conditions	[redacted]
3.4.6	Duration of the test	[redacted]
3.4.7	Test parameter	[redacted]
3.4.8	Examination / Sampling	[redacted]
3.4.9	Monitoring of TS concentration	[redacted]
3.4.10	Statistics	[redacted]
	4 RESULTS	
4.1	**Range finding test**	[redacted]
4.1.1	Concentrations	[redacted]
4.1.2	Number/ percentage of animals showing adverse effects	[redacted]

Section A7.4.3.4/01 Effects on reproduction and growth rate with an invertebrate species

Annex Point IIIA, XIII.2.4 *Daphnia magna*

4.1.3	Nature of adverse effects	[redacted]
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	[redacted]
4.2.2	Actual concentrations of test substance	[redacted]
4.2.3	Effect data	[redacted]
4.2.4	Concentration / response curve	[redacted]
4.2.5	Other effects	[redacted]
4.3	**Results of controls**	[redacted]
4.4	**Test with reference substance**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test was conducted according to EPA-FIFRA 72-4 (1982) and OECD 202 (1984). It was a flow-through test system and *Daphnia magna* was used as the test species.
5.2	**Results and discussion**	[redacted]
5.2.1	NOEC	49.9 µg/L, based upon the lack of significant mortality, reproductive or growth effects at this concentration at test termination (based on mean measured values)

Section A7.4.3.4/01 Effects on reproduction and growth rate with an invertebrate species

Annex Point IIIA, XIII.2.4 *Daphnia magna*

5.2.2	LOEC	99.3 µg/L, based upon mortality and significant reductions in growth and reproductive success at this concentration at test termination (based on mean measured values)
5.2.3	EC_{50}	133 µg/L at test termination, based on mortality mean measured values
5.3	**Conclusion**	[redacted] Based on the results, NOEC and LOEC were determined to be 49.9 µg/L and 99.3 µg/L, respectively. The EC50 was calculated to be 133 µg/L. All values based on mean measured test concentration.
5.3.1	Other Conclusions	[redacted]
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	No

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
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	

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.3.4/01-3: Test organism

Criteria	Details
Strain / Clone	*Daphnia magna*
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Criteria	Details
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.3.4/01-4: Test system

Criteria	Details
Test type	Flow-through
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.3.4/01-7: Effect data

Mean measured concentrations (µg/L)	Cumulative number of dead animals		Number of offspring	
	Per treatment	% Mortality	Total	Per reproductive day
Control	1	2	5118	9.4
Solvent Control	3	8	6955	13.3
7.59	1	2	5367	9.4
16.4	5	12	5890	11.2
29.5	1	2	5715	9.7
49.9	1	2	5703	9.6
99.3	10	25	2595	5.7
298	40	100	—	—

— = not determined because all daphnids were dead by day 10

Table A7.4.3.4/01-8: Toxicity values

Exposure period (Day)	EC_{50}[1] (µg/L)	95 % C.L. (µg/L)	NOEC[1] (µg/L)	LOEC (µg/L)	MATC[2] (µg/L)
7	142	99.3 – 298	ND	ND	ND
14	136	99.3 – 298	ND	ND	ND
21	133	99.3 – 298	49.9	99.3	> 49.9, < 99.3

[1] data are based on mean measured concentrations

[2] maximum acceptable toxicant concentration

ND = not determined

[redacted]

	[redacted]	[redacted]
[redacted]	[redacted]	
[redacted]	[redacted]	

[redacted]	[redacted]	[redacted]

Section A7.5.1.1/01 Annex Point IIA, VII.7.4 — Inhibition to microbial activity (terrestrial) Nitrogen Transformation test Carbon Transformation Test

Official use only

1 REFERENCE

1.1	**Reference**	Reis, K.-H. (2004): Effects of IPBC Technical on the Activity of the soil Microflora in the Laboratory; Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany; Study No. 17921080; expected finalization date April 2004; Doc. No. 841-001; (unpublished)
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, OECD No. 216, "Soil microorganisms: Nitrogen Transformation Test" (January 2000) OECD 217, "Soil microorganisms: Carbon Transformation Test" (January 2000).
2.2	**GLP**	[redacted]
2.3	**Deviations**	No

3 MATERIAL AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section A2.
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	[redacted]
3.1.5	Composition of Product	[redacted]
3.1.6	Further relevant properties	[redacted]
3.1.7	Method of analysis	[redacted]

Section A7.5.1.1/01
Annex Point IIA, VII.7.4

Inhibition to microbial activity (terrestrial)
Nitrogen Transformation test
Carbon Transformation Test

3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Testing procedure**	
3.4.1	Soil sample / inoculum / test organism	[redacted]
3.4.2	Test system	[redacted]
3.4.3	Application of TS	[redacted]
3.4.4	Test conditions	[redacted]
3.4.5	Test parameter	[redacted]
3.4.6	Analytical parameter	[redacted]
3.4.7	Duration of the test	[redacted]
3.4.8	Sampling	[redacted]
3.4.9	Monitoring of TS concentration	[redacted]
3.4.10	Controls	[redacted]
3.4.11	Statistics	[redacted]

4 RESULTS

4.1	**Range finding test**	[redacted]

Section A7.5.1.1/01 Annex Point IIA, VII.7.4	Inhibition to microbial activity (terrestrial) Nitrogen Transformation test Carbon Transformation Test

4.1.1	Concentration	[redacted]
4.1.2	Effect data	[redacted]
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	[redacted]
4.2.2	Actual concentrations of test substance	[redacted]
4.2.3	Growth curves	[redacted]
4.2.4	Cell concentration data	[redacted]
4.2.5	Concentration/ response curve	[redacted]

Section A7.5.1.1/01 Annex Point IIA, VII.7.4	Inhibition to microbial activity (terrestrial) Nitrogen Transformation test Carbon Transformation Test

4.2.6	Effect data	[redacted]
4.2.7	Other observed effects	[redacted]
4.3	**Results of controls**	[redacted]
4.4	**Test with reference substance**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

Section A7.5.1.1/01
Annex Point IIA, VII.7.4

Inhibition to microbial activity (terrestrial)
Nitrogen Transformation test
Carbon Transformation Test

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The test was conducted according to OECD 216 (Nitrogen Transformation Test) and OECD 217 (Carbon Transformation Test). The soil used in the study was according to the guidelines and was taken from a fallow grass land.

Carbon Transformation test:

Glucose induced respiration rate was determined by means of the BSB-Sensomat-System. The amount of O_2 consumed by the soil microflora was calculated from the decrease of pressure in the reaction vessel.

Nitrogen transformation test:

The nitrate content was determined after potassium chloride extraction of the soil using ion chromatography.

5.2 Results and discussion

[redacted]

5.2.1 NOEC

[redacted]

5.2.2 EC_{10}

[redacted]

5.2.3 EC_{50}

Carbon Transformation Test:

The EC_{50} was estimated to be 312.5 mg a.i./kg soil dry weight.

Nitrate Transformation Test:

No EC_{50} can be derived.

5.3 Conclusion

[redacted]

5.3.1 Other Conclusions

[redacted]

5.3.2 Reliability

[redacted]

5.3.3 Deficiencies

No

Evaluation by Competent Authorities

Section A7.5.1.1/01 **Inhibition to microbial activity (terrestrial)**
Annex Point IIA, VII.7.4 **Nitrogen Transformation test**
Carbon Transformation Test

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

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

Table A7.5.1.1/01-1: Microbial sample / Inoculum

Criteria	Details
Nature	Soil sample

Criteria	Details
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Criteria	Details
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.5.1.1/01-2: Test organism

Criteria	Details
Species	n.a.
Strain	n.a.
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

[redacted]

Section A7.5.1.2/01 Earthworm, acute toxicity test

Annex Point IIIA, XIII.3.2 ***Eisenia fetida***

Official use only

1 REFERENCE

1.1	**Reference**	Lührs, U. (2004): Acute Toxicity (14 Days) of IPBC Technical to the Earthworm *Eisenia fetida* in Artificial Soil; Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany; Study No.: 17922021; 22 March 2004; Doc. No. 833-001; (unpublished)
1.2	**Data protection**	Yes
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**	[redacted] OECD 207; EU Commission Directive 88/303/EEC, Part C8; ISO 11268-1, 1993
2.2	**GLP**	[redacted]
2.3	**Deviations**	No

3 MATERIAL AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section 2
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	[redacted]
3.1.5	Composition of Product	[redacted]
3.1.6	Further relevant properties	[redacted]
3.1.7	Method of analysis	[redacted]
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]

Section A7.5.1.2/01 Earthworm, acute toxicity test
Annex Point IIIA, XIII.3.2 ***Eisenia fetida***

3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Testing procedure**	
3.4.1	Preparation of the test substance	[redacted]
3.4.2	Application of the test substance	[redacted]
3.4.3	Test organisms	[redacted]
3.4.4	Test system	[redacted]
3.4.5	Test conditions	[redacted]
3.4.6	Test duration	[redacted]
3.4.7	Test parameter	[redacted]
3.4.8	Examination	[redacted]
3.4.9	Monitoring of test substance concentration	[redacted]
3.4.10	Statistics	[redacted]

4 RESULTS

4.1	**Filter paper test**	[redacted]
4.1.1	Concentration	[redacted]
4.1.2	Number/ percentage of animals showing adverse effects	[redacted]
4.1.3	Nature of adverse effects	[redacted]

Section A7.5.1.2/01 **Earthworm, acute toxicity test**
Annex Point IIIA, XIII.3.2 ***Eisenia fetida***

4.2 Soil test

4.2.1 Initial concentrations of test substance

4.2.2 Effect data (Mortality)

4.2.3 Concentration / effect curve

4.2.4 Other effects

4.3 Results of controls

4.3.1 Mortality

4.3.2 Number/ percentage of earthworms showing adverse effects

4.3.3 Nature of adverse effects

4.4 Test with reference substance

4.4.1 Concentrations

4.4.2 Results

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The acute toxicity of IPBC (technical) to earthworms, *Eisenia fetida*, was determined in a 14-day soil exposure laboratory study conducted according to the following guidelines: OECD 207; EU Commission Directive 88/303/EEC, Part C8 and ISO 11268-1 (1993).

Section A7.5.1.2/01 Earthworm, acute toxicity test
Annex Point IIIA, XIII.3.2 *Eisenia fetida*

5.2	**Results and discussion**	
5.2.1	LC_0	≥ 1000 mg/kg dry weight artificial soil, (the highest concentration tested)
5.2.2	LC_{50}	≥ 1000 mg/kg dry weight artificial soil
5.2.3	LC_{100}	Not applicable
5.3	**Conclusion**	[redacted] The LC50 was calculated to be ≥1000 mg/kg dry weight artificial soil.
5.3.1	Other Conclusions	[redacted]
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	No

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Section A7.5.1.2/01 Earthworm, acute toxicity test
Annex Point IIIA, XIII.3.2 ***Eisenia fetida***

	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	

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.5.1.1/01-2: Test organisms

Criteria	Details
Species/strain	*Eisenia fetidae* (Savigny 1826)

Criteria	Details
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]

[redacted]	[redacted]			
	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

Table A7.5.1.2/01-6: Effect data

	14 d [mg/kg soil][1]	95 % C.L.
LC_0	n.a.	n.a.
LC_{50}	≥1000 (n)	n.a.
LC_{100}	n.a.	n.a.

[1] n = effect data are based on nominal concentrations

[redacted]

	[redacted]	[redacted]
[redacted]	[redacted]	

Section 7.5.1.3/01 Terrestrial plant toxicity

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

			Official use only
		1 REFERENCE	
1.1	**Reference**	Spatz, B. (2004): Effects of IPBC Technical on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Test; Institut für Biologische Analytik und Consulting IBACON, Rossdorf, Germany; Study No.: 17923084; expected finalization date April 2004; Doc. No. 851-001; (unpublished)	
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, OECD 208 (proposal for updating guideline 208, draft document July 2000)	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	No	
		3 MATERIAL AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	As given in section 2	
3.1.3	Purity	[redacted]	
3.1.4	Description of test substance	[redacted]	
3.1.5	Composition of Product	[redacted]	
3.1.6	Further relevant properties	[redacted]	
3.1.7	Method of analysis	[redacted]	

Section 7.5.1.3/01 Terrestrial plant toxicity

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

3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Testing procedure**	
3.4.1	Dilution water	[redacted]
3.4.2	Test plants	[redacted]
3.4.3	Test system	[redacted]
3.4.4	Test conditions	[redacted]
3.4.5	Duration of the test	[redacted]
3.4.6	Test parameter	[redacted]
3.4.7	Sampling	[redacted]
3.4.8	Method of analysis of the plant material	[redacted]
3.4.9	Quality control	[redacted]
3.4.10	Statistics	[redacted]

4 RESULTS

4.1	**Range finding test**	
4.1.1	Concentration	[redacted]
4.1.2	Effect data	[redacted]
4.2	**Results test substance**	

Section 7.5.1.3/01 Terrestrial plant toxicity

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

4.2.1	Applied initial concentration	[redacted]
4.2.2	Phytotoxicity rating	[redacted]
4.2.3	Plant height	[redacted]
4.2.4	Plant dry weights	[redacted]
4.2.5	Root dry weights	[redacted]
4.2.6	Root length	[redacted]
4.2.7	Number of dead plants	[redacted]
4.2.8	Effect data	[redacted]
4.2.9	Concentration / response curve	[redacted]
4.2.10	Other effects	[redacted]
4.3	**Results of controls**	
4.3.1	Number/ percentage of plants showing adverse effects	[redacted]
4.3.2	Nature of adverse effects	[redacted]
4.4	**Test with reference substance**	[redacted]

Section 7.5.1.3/01 Terrestrial plant toxicity
Annex Point IIIA, XIII 3.4 ***Brassica napus / Glycine max / Avena sativa***

4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The effects on the seedling emergence and seedling growth of IPBC (Technical) on terrestrial non-target plants were tested according to the following guideline: OECD Guideline for the Testing of Chemicals, Proposal for Updating Guideline 208, Draft Document (July 2000).

The test was carried out on 3 species (*Avena sativa*, *Glycine max* and *Brassica napus*) out of 3 different plant families. Test parameters were fresh weight of the plants, germination, mortality and phytotoxicity.

5.2 Results and discussion

5.2.1 EC_{20}

The EC_{20} was not calculated.

Avena sativa:

EC_{25}: 3.11 mg ai/kg dry soil (95% C.L. 1.86 - 4.01 mg ai/kg dry soil)

Glycine max:

EC_{25}: 1.64 mg ai/kg dry soil (95% C.L. 0.24 - 3.62 mg ai/kg dry soil)

Brassica napus:

EC_{25}: 6.18 mg ai/kg dry soil (95% C.L. 1.59 - 9.80 mg ai/kg dry soil)

5.2.2 EC_{50}

Avena sativa:

EC_{50}: 4.92 mg ai/kg dry soil (95% C.L. 3.77 - 6.44 mg ai/kg dry soil)

Glycine max:

EC_{50}: 6.89 mg ai/kg dry soil (95% C.L. 2.83 - 10.66 mg ai/kg dry soil)

Brassica napus::

EC_{50}: 12.12 mg ai/kg dry soil (95% C.L. 6.84 - 21.27 mg ai/kg dry soil)

5.2.3 EC_{80}

The EC_{80} was not calculated.

5.3 Conclusion

[redacted]

The EC50 was calculated to be 4.92 mg ai/kg dry soil for *Avena sativa*, 6.89 mg ai/kg dry soil for *Glycine max* and 12.12 mg ai/kg dry soil for *Brassica napus*.

5.3.1	Other Conclusions	[redacted]
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	No

Section 7.5.1.3/01 Terrestrial plant toxicity

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

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

	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	

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

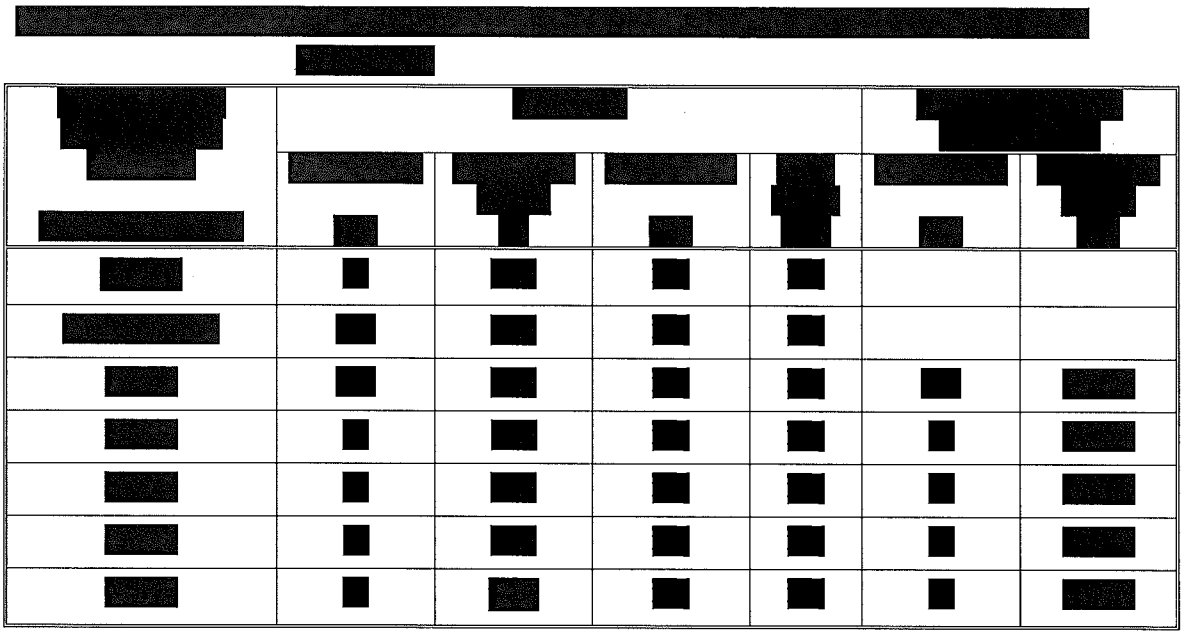
Table A7.5.1.3/01-3: Test plants

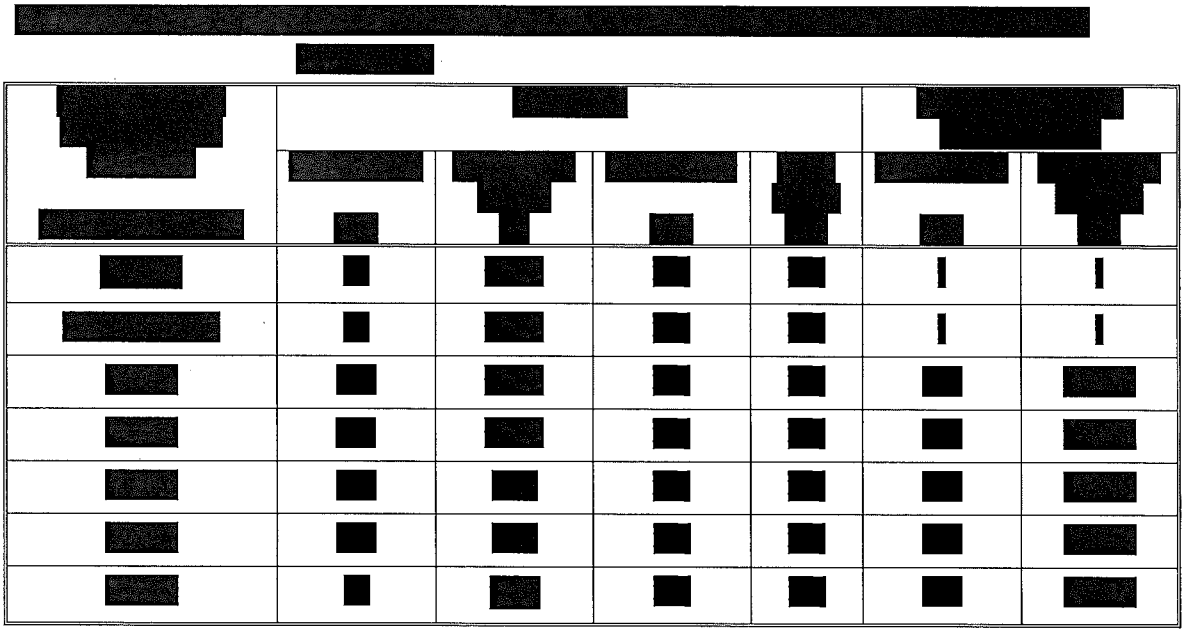
	Family	Species	Common name	[redacted]
Dicotyledonae	Brassicaceae	*Brassica napus*	Oilseed Rape	
	Fabaceae	*Glycine max*	Soybean	
Monocotyledonae	Poaceae	*Avena sativa*	Oat	

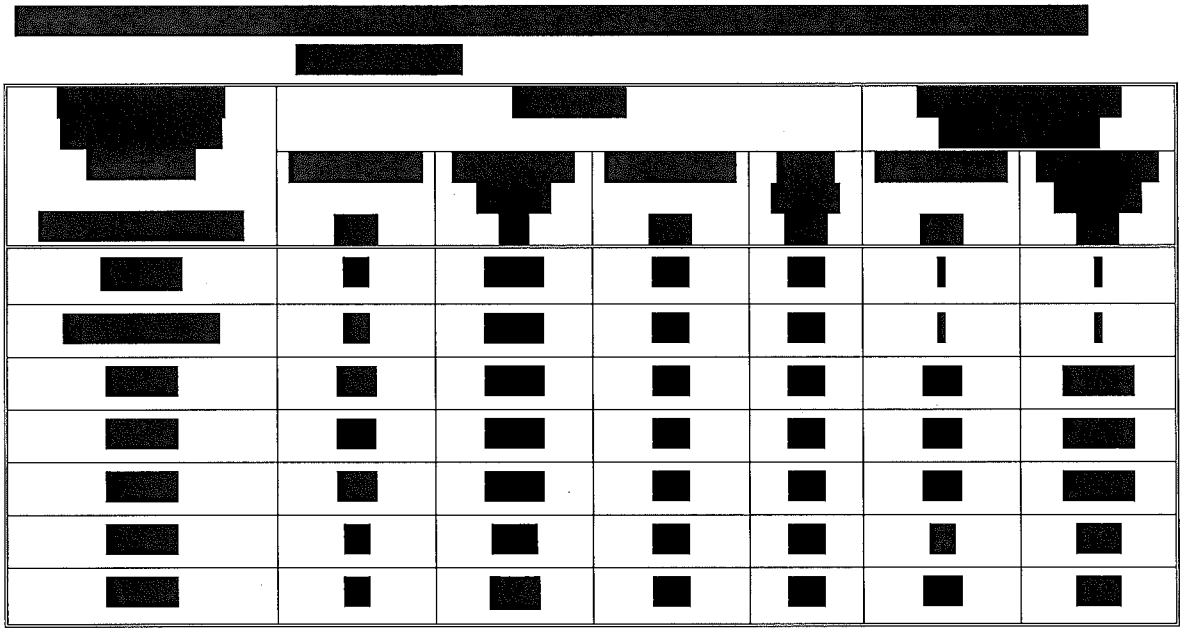
[redacted]

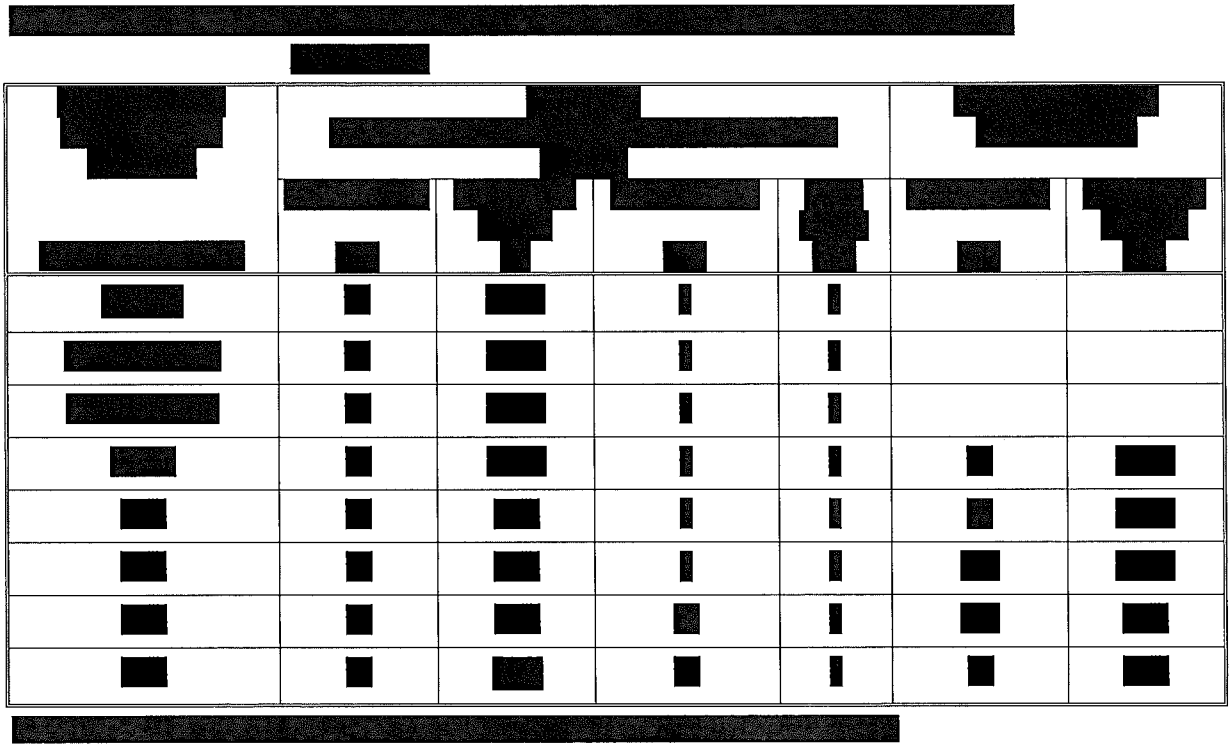
[redacted]

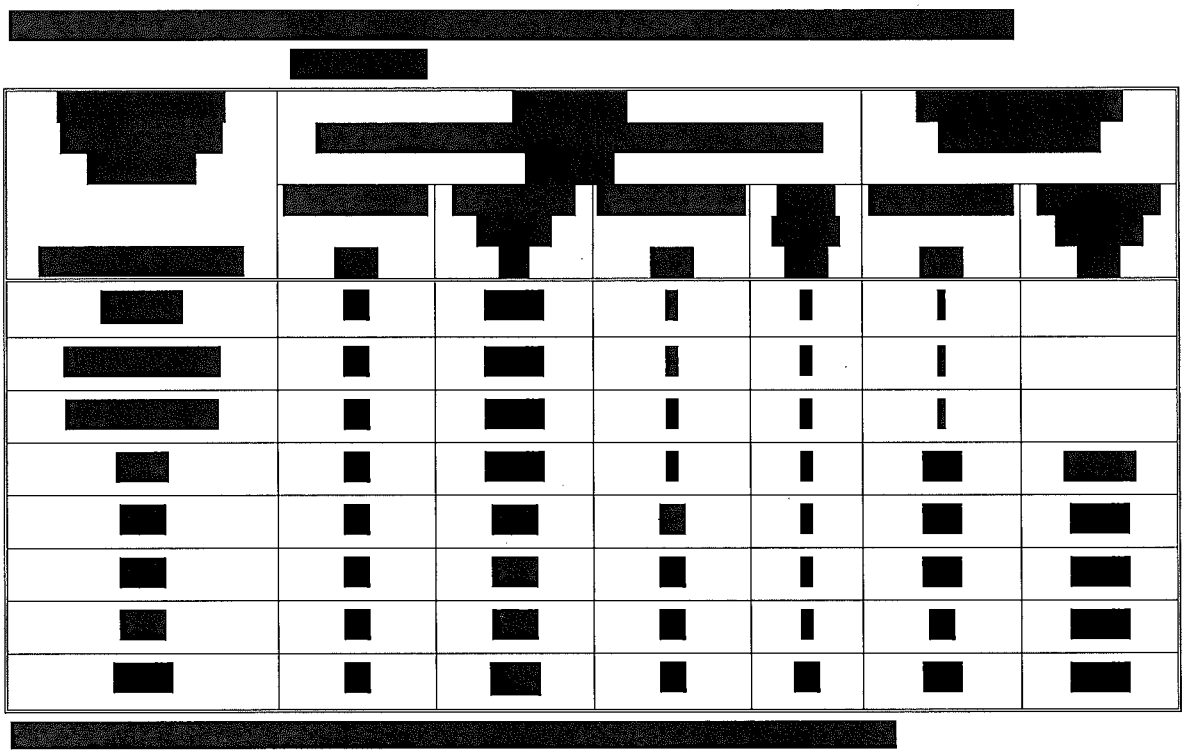
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

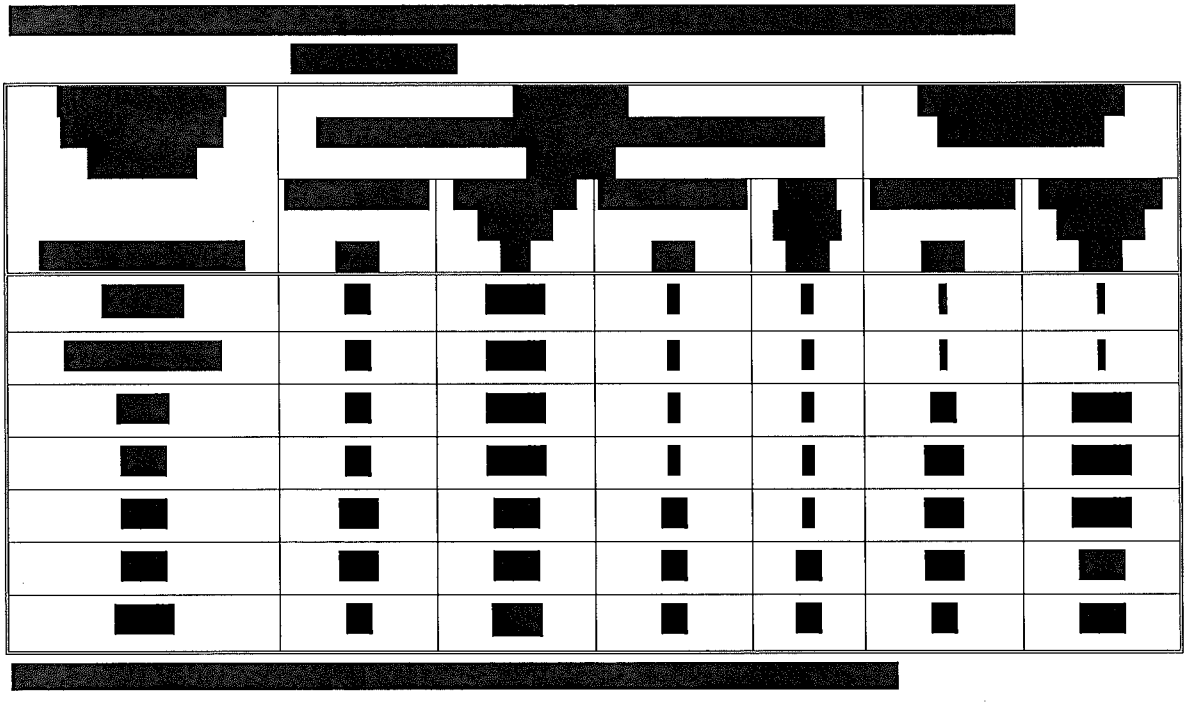












[redacted]

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]	[redacted]	

Section A7.5.2/01 Addendum 1 to dossier	Terrestrial tests, long-term tests

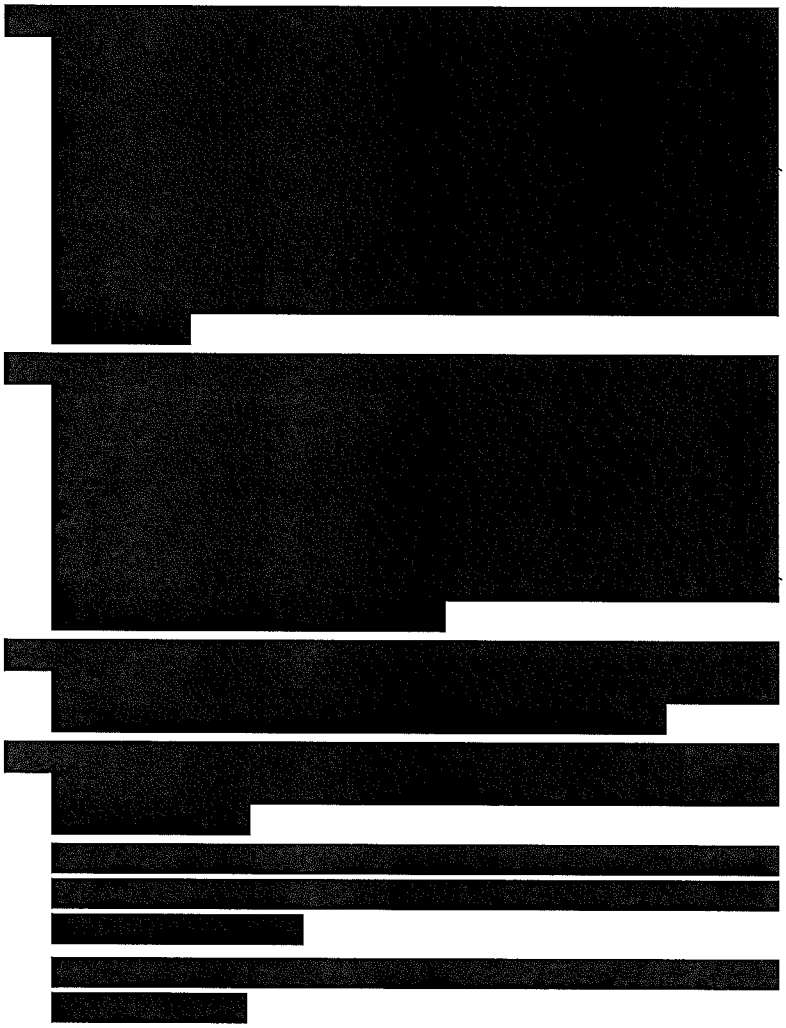
JUSTIFICATION FOR NON-SUBMISSION OF DATA

Official use only

Scientifically unjustified

Detailed justification:

According to the BPD 98/8/EC and the TNsG on data requirements, long-term terrestrial tests are required if the risk assessment for the terrestrial compartment, based on the results of the acute toxicity tests still indicates concern for the terrestrial compartment or if there is long term exposure.



Consequently, long term tests are not warranted because they do not address the point in question, i.e. continuous exposure.

Section A7.5.2/01 Addendum 1 to dossier	Terrestrial tests, long-term tests
Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*

Section A7.5.2.1 Annex Point IIIA, XIII.3.2	Reproduction study with earthworm or other soil non-target organisms	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Scientifically unjustified	
Detailed justification:	According to the BPD 98/8/EC and the TNsG on data requirements, long-term terrestrial tests are required if the risk assessment for the terrestrial compartment, based on the results of the acute toxicity tests still indicates a concern for the terrestrial compartment. [redacted] Therefore, no further testing is required.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	

Section A7.5.2.2 Annex Point IIIA, XIII.3.2	Long-term test with terrestrial plants	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA **Scientifically unjustified**	Official use only
Detailed justification:	According to the BPD 98/8/EC and the TNsG on data requirements, long-term terrestrial tests are required if the risk assessment for the terrestrial compartment, based on the results of the acute toxicity tests still indicates a concern for the terrestrial compartment. [redacted] • [redacted]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	

Section A7.5.3.1.1 Annex Point IIIA, XIII.1.1	Acute oral toxicity to birds	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 8 (wood preservatives).	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	

Section A7.5.3.1.2 Annex Point IIIA, XIII.1.2	Short-term toxicity to birds	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 8 (wood preservatives).	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	

Section A7.5.3.1.3 Annex Point IIIA, XIII.1.3	Effects on reproduction of birds	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 8 (wood preservatives).	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	

Section A7.5.4.1. Annex Point IIIA, XIII.3.1	Acute toxicity to honeybees and other beneficial arthropods
	JUSTIFICATION FOR NON-SUBMISSION OF DATA Official use only
	Other justification
Detailed justification:	Not required for Product type 8 (wood preservatives).
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*24. June 05*
Evaluation of applicant's justification	*Applicant's justification is OK*
Conclusion	*Applicant's justification is acceptable*
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*

Section A7.5.5 Annex Point IIA, VII.7.5	Bioconcentration in terrestrial organisms	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Scientifically unjustified	
Detailed justification:	[redacted]According to the BPD 98/8/EC and the TNsG on data requirements, the intrinsic potential for bio-concentration in terrestrial organisms should be estimated on the basis of physical and chemical properties. The most important indicator of the bio-accumulation potential is the octanol/water partition coefficient. According to the TGD on Risk Assessment, the bio-concentration potential of an active substance should be determined, when the log Kow is greater or equal to 3. [redacted]	
Evaluation by Competent Authorities		
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	

Section A7.5.6 Annex Point IIIA, XIII.3	Effects on other terrestrial non-target organisms	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	According to the BPD 98/8/EC and the TNsG on data requirements, further tests with other terrestrial non-target organisms may be required if the risk assessment based on long-term terrestrial tests show that there is still a concern for the terrestrial compartment. [redacted] • [redacted]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	

Section A7.5.7.1.1 Annex Point IIIA, XIII.3.4	Acute oral toxicity to mammals	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 8 (wood preservatives).	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	

Section A7.5.7.1.2 Annex Point IIIA, XIII.3.4	Short-term toxicity to mammals	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 8 (wood preservatives).	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	

Section A7.5.7.1.3 Annex Point IIIA, XIII.3.4	Effects on reproduction of mammals	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 8 (wood preservatives).	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	

Section A7.1.2.1.1 **Annex Point IIIA, XI.-2.1**	**Aerobic biodegradation**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	According to the TNsG on data requirements, an aerobic simulation test is required if the biocide enters a sewage treatment plant before release to the environment. [redacted] Therefore, a study on aerobic biodegradation is not regarded to be warranted.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A8.1 Annex Point IIA,VIII.8.1	Recommended methods and precautions concerning handling, use, storage, transport or fire	
		Official use only

Handling and storage
Store in original container in a dry place.
Do not allow product temperature to exceed 40 °C and do not expose to direct light.
Ventilate room well, using suitably positioned air extractors if necessary.
Vent waste air only via suitable separators or scrubbers.
Precautions should generally be taken against electrostatic charges according to the equipment used and the way the product is handled and packaged.
VCI storage class: 11
Storage period 12 months.

Exposure controls/Personal protection
Respiratory protection: combination filter, e.g. DIN 3181 ABEK-P2, if product forms vapours or dust.
Eye protection: closely fitting goggles.
Hand protection: e.g. gloves of rubber or PVC. After contamination with product change the gloves immediately and remove them according to relevant national and local regulations.
Other protective equipment: Wear protective clothing and boots.
Do not breathe dust.
Avoid contact with eyes and skin.
Keep away from food and drink stuffs.
Do not eat, drink or smoke at work.
Wash hands before breaks and at end of work and use skin-protecting ointment.

Transport information
Transport on road/by rail
ADR/RID: class 9 Miscellaneous dangerous substances and articles.
Danger code (Kemler): 90
UN-Number: 3077
Packaging group: III
Hazard label: 9
Description of goods: Environmentally hazardous substance, solid, N.O.S. (3-iodo-2-2propynyl butylcarbamate)

Maritime transport
IMDG: class 9
UN-Number: 3077
Packaging group: III
Label: 9
EMS number: F-A, S-F
Marine pollutant: Yes
Proper shipping name: Environmentally hazardous substance, solid, N.O.S. (3-iodo-2-2propynyl butylcarbamate)

Air transport
ICAO/IATA: class 9
UN-Number: 3077
Packaging group: III
Label: 9
Proper shipping name: Environmentally hazardous substance, solid, N.O.S. (3-iodo-2-2propynyl butylcarbamate)

Section A8.1 Annex Point IIA,VIII.8.1	Recommended methods and precautions concerning handling, use, storage, transport or fire
	Declaration for shipment by air: Environmentally hazardous substance, solid, n.o.s. (JODBUTYLCARBAMATE) Other information: Environmentally hazardous substance (GGVSE, RID/ADR). Keep away from foodstuffs, acids and alkalis. Fire-fighting measures Extinguishing media: All extinguishing materials are suitable. Agents: Alcohol resistant foam, carbon dioxide, dry chemicals, water spray. Cool undamaged containers with water. Firemen have to wear self-contained breathing apparatus. Protective equipment: Hard hat, butyl rubber boots and gloves, splash proof goggles, impervious clothing an full face shield.
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A8.2 Annex Point IIA,VIII.8.2	In case of fire, nature of reaction products, combustion gases, etc.	
		Official use only
	Fire-fighting measures Extinguishing media: All extinguishing materials are suitable: Alcohol foam, carbon dioxide, dry chemical, water spray. Take note of surrounding materials. Cool undamaged containers with water. Firemen have to wear self-contained breathing apparatus. Additional protective clothing may be worn to prevent personal contact. Includes: hard hat, butyl rubber boots and gloves, splash-proof goggles, impervious clothing. Ignition temperature: 385 °C Combustibility: BZ 1 = no ignition. Hazardous decomposition products: No hazardous decomposition products when stored and handled correctly. Formation of carbon monoxide, carbon dioxide, nitrogen oxides, iodine-vapours and other toxic gases in the event of fire or during thermal decomposition. Hazardous reactions: No hazardous reaction when used as directed. Further information: Incompatibility with strong acids and alkalis	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A8.3 Emergency measures in case of an accident

Annex Point IIA,VIII.8.3

Official use only

Evacuate all non-essential personnel. Hazardous concentrations in air may be found in local spill area and immediately downwind. Utilise emergency response personal protective equipment prior to the start of any response. Stop source of spill as soon as possible. Notify site or duty manager. If large spill notify the emergency services, National Environment Agency. Inform all downstream users of possible contamination.

Measures for cleaning/collecting
Divert water flow around spill if possible and safe to do so. If unable to divert, create a filtration dam to remove material. Remove/clean material by use of vacuum system/pumps or sweep up. Containerise an label properly for disposal as a hazardous waste.

Hazards identification
Eyes:
Exposure may cause severe irritation and/or chemical burns with corneal damage. Impairment of vision is possible. Immediately flush with large amounts of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Seek medical attention at once.

Skin:
Acute exposure may cause transient redness and irritation. Immediately flush with water for 15 minutes. Wash contaminated skin with soap and water. If irritation develops, seek medical attention. Clothing should be laundered before re-use.

Ingestion:
If ingested, gastro-enteritis may occur with nauseam vomiting, lethargy, and diarrhoea. Immediately drink large quantities of water. Rinse the mouth with plenty of water. Seek medical attention at once. DO NOT give anything by mouth if the person is unconscious or is having convulsions.

Inhalation:
Acute exposure may cause mild and transient irritation to the respirator tract. If person experiences nausea, tremors, ataxia, convulsions, headache or dizziness, move to fresh air until these symptoms disappear. Support respiration if needed, keep the patient calm and protect him from loss of warmth. Seek medical attention.

Note to medical personnel:
Exposure to highly exaggerated concentrations via inhalation may result in the inhibition of acetylcholinesterase and produce related symptoms which may include blurred vision, nausea, vomiting, abdominal cramps, excessive salivation and profuse sweating. Laboured breathing, tremors, muscle twitching, staggered gait and headache may also occur.

First-aid measures
GENERAL INFORMATION: Remove all contaminated clothing. Also heed the risks to your own person.

Therapeutic measures:
Basic aid, decontamination, symptomatic treatment.

Section A8.3 Annex Point IIA,VIII.8.3	Emergency measures in case of an accident
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A8.4 Annex Point IIA,VIII.8.4	Possibility of destruction or decontamination following release in or on the following: (a) air (b) water, including drinking water (c) soil	
		Official use only
	Air: If dusting occurs, wear an approved full-face respirator. Dust/vapours may be suppressed by the use of a water fog. All water utilised to assist in fume suppression, decontamination or fire suppression may be contaminated and must be contained before disposal and or treatment as a hazardous waste. Water: This material is lighter than and slightly soluble in water Notify all downstream users of possible contamination. Divert water flow around spill if possible and safe to dos so. If unable to divert, create a filtration dam to remove material. Remove/clean up material by use of a vacuum system/pumps or sweep up. Containerise and label properly for disposal as a hazardous waste. Land spill: Remove/clean up material by use of a vacuum system/pumps or sweep up. Containerise and label properly for disposal as a hazardous waste.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A8.5.2 Annex Point IIA,VIII.8.5.2	Possibility of neutralisation of effects
	Official use only
	Please refer to Doc. IIIA, Section A8.5
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	
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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 A8.5.3 **Annex Point IIA,VIII.8.5.3**	**Conditions for controlled discharge including leachate qualities on disposal**
	Official use only
	Please refer to Doc. IIIA, Section A8.5
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A8.5.4	**Conditions for controlled incineration**
Annex Point IIA,VIII.8.5.4	
	Official use only
	Please refer to Doc. IIIA, Section A8.5
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A8.5.1 Annex Point IIA,VIII.8.5.1	Possibility of re-use or recycling
	Official use only
	Please refer to Doc. IIIA, Section A8.5
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A8.5 Annex Point IIA, VIII.8.5	Procedures for waste management of the active substance for industry or professional users	
		Official use only
	Disposal considerations Examine possibilities for re-utilisation. Package product wastes. Close and label the waste receptacles and, likewise, any uncleaned empty containers. Dispose of them at a suitable waste incineration plant in accordance with the official regulations. Where large quantities are concerned, consult the supplier. When uncleaned empty containers are passed on, the recipient must be warned of any possible hazard that may be caused by residues. For disposal within the EC, the appropriate code according to the European Waste Catalogue (EWC) should be used. It is among the tasks of the polluter to assign the waste to waste codes specific to industrial sectors and processes according to the European Waste Catalogue.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A8.6 **Annex Point IIA,VIII.8.6**	**Observations on undesirable or unintended side effects, for example, on beneficial and other non-target organisms**
	Official use only
	There are no observations on undesirable or unintended side effects.
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A8.7 **Annex Point IIIA,VIII.1**	**Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of ground water against pollution caused by certain dangerous substances (OJ No L20,26.1,1980, p.43)**
	Official use only
	IPBC [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	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

9 Classification and labelling

The following classification and labelling for the active substance IPBC is proposed By the RMS:

Hazard symbol(s):		T, N
- Indications of danger:		Harmful, Dangerous for the environment
Risk phrases:	R22	Harmful if swallowed.
	R23	Toxic by inhalation
	R41	Risk of serious damage to the eye
	R43	May cause sensitization by skin contact.
	R50	Very toxic to aquatic organisms.
Safety phrases:		
	S1	Keep locked up.
	S2	Keep out of the reach of children.
	S22	Do not breath dust.
	S24	Avoid contact with skin.
	S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
	S37/39	Wear suitable gloves and eye/face protection.
	S38	In case of insufficient ventilation, wear suitable respiratory equipment.
	S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
	S46	If swallowed, seek medical advice immediately and show this container or label.
	S61	Avoid release to the environment. Refer to special instructions/Safety data sheets.

Justifications

The above proposed classification and labelling requirements are according to the RMS in line with the findings presented in the dossier for the relevant physico-chemical, toxicological and ecotoxicological studies with IPBC.

However, it must be stressed that a common agreement among the Member States could not be reached about the risk phrase R53 and this question was therefore send to the CL group.

The RMS does not agree to label IPBC with R53 because there are a valid biodegradation test in soil which shows rapid biodegradation. The test was done with no pre-exposure of the soil micro-organism and at environmental realistic concentrations of the test substance. The substance is ultimately degraded within 28 days with a half-life of less than 5 days at 12°C. However, as no agreement could be reached at the TM III-07 about this issue the question was send to the CL group.

The labelling and classification triggering findings are:

for R22
LD_{50} (rat, oral): 300 – 500 mg/kg bw

for R23
Highly toxic with an LC_{50} of about 0.67 mg/L for dust with respirable particle size (MMAD 4.3 µm) and of about 0.78 mg/L for a liquid aerosol with respirable droplet size (MMAD 2.4 µm); and an LC_{50} of about 0.88 mg/L for dust (non-micronised) with 19.2-26.7% of the particles being of a respirable particle size of 6 µm (MMAD of 9.6-14.2 µm) and of about 0.67 mg/L for a combination of micronised and non-micronised dust. Following administration of particles with technical IPBC (particle size mot measured in this particular study) claimed by the notifier to be non-respirable an $LC_{50} > 6.89$ mg/L was determined.
RMS proposes classification as toxic with R23: Toxic by inhalation for technical IPBC regardless of the particle size because of several uncertainties. First of all the particle size of IPBC in the study by [redacted] 1985, which is the only study out of three which is not leading to the classification as toxic, was not measured so the actual MMAD and proportion of particle less than 10 µm is uncertain and could be different from the one stated in Flack 2001. Furthermore in the study (Flack, 2001, Doc. No. 111-001) measuring the particle size of technical IPBC used in the representative products and products on the market ≤ 5% of the particles were smaller than 10 µm but it was not further subdivided into smaller particle sizes and percentage distributions. It should be recognised that in the non-key study the MMAD was 9.6-14.2 µm, 19.2-26.7% of the particles being of a particle size of less than 6 µm and lead to an LC_{50} of about 0.88 mg/L and therefore RMS is reluctant to disregard the fact that the MMAD in this study is of comparable particle size (10 µm) with 5% of the particles in technical IPBC being used in products on the market.

for R41
The observed effects persisted throughout the 7 day observation period.

for R43
The skin sensitising potential of IPBC observed in 3 of 4 GPMTs is supported by data from human case reports.

for R50

Fish acute:	
96 h, acute LC_{50} (*Oncorhynchus mykiss*):	67 to 72 µg/L
For algea:	
72 h, acute EC_{50} (*Scenedesmus subspicatus*):	22 µg/L
For daphnia:	
48 h, acute EC_{50} (*Daphnia magna)* :	160 µg/L