

Section A7.4.1.1 Acute toxicity to fish (01)**Annex Point IIA VII.7.1** *Leiostomus xanthurus* (spot fish)

			Official use only
1 REFERENCE			
1.1 Reference	█ (1964): Effects of pesticides on marine animals. United States Department of the Interior, Fish and Wildlife Service, Bureau of Commercial Fisheries Biological Laboratory, Gulf Breeze, Florida.		
1.2 Data protection	Yes		
1.2.1 Data owner	United States Department of the Interior, Fish and Wildlife Service, Bureau of Commercial Fisheries		
1.2.2 Companies with letter of access	Not applicable		
1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA		
2 GUIDELINES AND QUALITY ASSURANCE			
2.1 Guideline study	No		
2.2 GLP	No		X
2.3 Deviations	-		
3 MATERIALS AND METHODS			
3.1 Test material	BAYER 47531 (= dichlofluanid)		X
3.1.1 Lot/Batch number	-		
3.1.2 Specification	-		
3.1.3 Purity	-		
3.1.4 Composition of Product	-		
3.1.5 Further relevant properties	-		
3.1.6 Method of analysis	-		X
3.2 Preparation of TS solution for poorly soluble or volatile test substances	Stock solution of the pesticides are made up in acetone and metered into the flowing sea-water to obtain the desired concentration (several concentrations tested).		X
3.3 Reference substance	A group of pesticides was tested for the study, however no reference substance was used.		
3.3.1 Method of analysis for reference substance	-		
3.4 Testing procedure			
3.4.1 Dilution water	Seawater, further details not given		
3.4.2 Test organisms	Juveniles of spot fish; the fish were captured in local waters		X
3.4.3 Test system	Flowing water; 29 ‰ salinity; 13 °C was the average temperature of water		

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3.4.4	Test conditions	-	X
3.4.5	Duration of the test	48 hours	X
3.4.6	Test parameter	Mortality	
3.4.7	Sampling	24 and 48 hours	
3.4.8	Monitoring of TS concentration	-	
3.4.9	Statistics	-	
4 RESULTS			
4.1	Limit Test	Not performed	
4.1.1	Concentration	-	
4.1.2	Number/ percentage of animals showing adverse effects	-	
4.1.3	Nature of adverse effects	-	
4.2	Results test substance		
4.2.1	Initial concentrations of test substance	-	
4.2.2	Actual concentrations of test substance	-	
4.2.3	Effect data (Mortality)	24h-EC ₅₀ = 0.032 mg/L 48h-EC ₅₀ = 0.032 mg/L	X
4.2.4	Concentration / response curve	Curve is not given in the report	
4.2.5	Other effects	-	
4.3	Results of controls		X
4.3.1	Number/ percentage of animals showing adverse effects	-	
4.3.2	Nature of adverse effects	-	
4.4	Test with reference substance	Not performed	
4.4.1	Concentrations	-	

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4.4.2 Results -

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods The acute toxicity of a group of pesticides, e.g. dichlofluanid was tested on spot fish in a flow-through test system using seawater.

5.2 Results and discussion5.2.1 96h-LC₀ -5.2.2 96h-LC₅₀ 48h-EC₅₀ = 0.032 mg/L5.2.3 96h-LC₁₀₀ -**5.3 Conclusion**

The test cannot be considered as valid in the sense of current requirements, since many details are missing. However, the study was done by a laboratory of the Fish and Wildlife Service, which is part of the United States Department of Interior. It was part of a testing program of many pesticides. A flow through test design was applied. There is no indication that the results presented in the paper are not reliable (e.g. prior hydrolysis of the active to DMSA would result in much higher EC₅₀ values = lower aquatic toxicity).

5.3.1 Other Conclusions -

5.3.2 Reliability 3

5.3.3 Deficiencies Study details are missing, non-GLP

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Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	18/11/2013
Materials and Methods	<p>Applicant's version is acceptable noting the following:</p> <p>2.2 - The study was not conducted to GLP but pre-dates biocide GLP requirements.</p> <p>3.1 – The only information on the test item is the name of the substance. There is no information on batch number, purity etc.</p> <p>3.1.6 – There was no analytical verification reported for the test item.</p> <p>3.2 – Acetone was used as a solvent but it is not reported if there was a solvent control.</p> <p>3.4.2 – There are no details on the test organisms – e.g. length and weight. It is not reported whether there was an acclimation period or how many organisms were used per dose level.</p> <p>3.4.4 – Test conditions are not reported.</p> <p>3.4.5 – Study duration was 48 h, which is less than the standard 96 h used for acute fish toxicity tests. A longer duration study may result in a lower LC50.</p>
Results and discussion	<p>Applicant's version is acceptable noting the following:</p> <p>4.2.3 – Effects data is not reported, only a LC50 value. Additionally there is no information on sublethal effects. The statistical method used to derive the LC50 is not reported.</p> <p>4.3 – Control mortality is not reported.</p>
Conclusion	Applicant's version is acceptable.
Reliability	3
Acceptability	Not acceptable
	There is insufficient information as to study methodology and results to determine the validity of the study. Therefore, the study cannot be considered valid.
Remarks	The referenced paper is a summary of results from aquatic organism toxicity tests for a range of pesticides and species. It contains minimal information on methodology and results are only reported in terms of an overall endpoint. All endpoints and data presented in the summary and tables have been checked against the original summary and are correct.
	COMMENTS FROM ...
Date	<i>Give date of comments submitted</i>

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Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	