

Section A7.4.1.2 Acute toxicity to invertebrates (1)

Annex Point IIA VII.7.2 Oyster

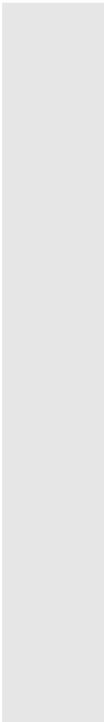
			Official use only
1 REFERENCE			
1.1 Reference	Lowe, JI (1964): Effects of pesticides on marine animals. United States Department of the Interior, Fish and Wildlife Service, Bureau of Commercial Fisheries Biological Laboratory, Gulf Breeze, Florida.		
1.2 Data protection	Yes		
1.2.1 Data owner	United States Department of the Interior, Fish and Wildlife Service, Bureau of Commercial Fisheries Biological Laboratory,		
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	Small oysters; the edge of the shell of each oyster was ground evenly at the beginning of the test so that new shell growth was objectively measured		X

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3.4.3	Test system	Test was performed in flowing sea-water aquaria; 25 % salinity; 29 °C was the average temperature of water	
3.4.4	Test conditions	-	X
3.4.5	Duration of the test	96 hours	
3.4.6	Test parameter	Shell growth; average shell growth of oysters in each test concentration is compared with a group of control oysters	
3.4.7	Sampling	-	
3.4.8	Monitoring of TS concentration	-	
3.4.9	Statistics	Graphical interpolation	
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 (Immobilisation)		X
4.2.4	Concentration / response curve	Curve is not given in the report	
4.2.5	Other effects	Recovery rate of shell growth is determined by transferring surviving experimental oysters to unpolluted water until their growth rate equals that of control oysters. 5 weeks were needed for recovery.	
4.3	Results of controls	-	X
4.4	Test with reference substance	No	
4.4.1	Concentrations	-	
4.4.2	Results	-	

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		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	Materials and methods	Acute toxicity test to oysters was performed under flow-through conditions to dichlofluanid over a 96 hour period.
5.2	Results and discussion	-
5.2.1	NOEC	-
5.2.2	EC ₅₀	96h-EC ₅₀ = 0.059 mg/L and 5 weeks as recovery period
5.2.3	EC ₁₀₀	-
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 EC ₅₀ values = lower aquatic toxicity).
5.3.1	Reliability	3
5.3.2	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. 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>
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 sub lethal effects. Statistical method used to derive the EC50 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>
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>

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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	