

Section 7.4.3.2b Annex Point IIIA 13.2.2	Effects on reproduction and growth rate on an appropriate <u>marine</u> species of fish	
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data []	Technically not feasible [X]	Scientifically unjustified [X]
Limited exposure [X]	Other justification [X].	
Detailed justification:	<p>A test on reproduction and growth rate on an appropriate marine species of fish was not performed due to the following reasons:</p> <p>In seawater the active dichlofluanid is very rapidly hydrolysed and detoxified to DMSA (Dimethylaminosulfanilide, CAS 4710-17-2). The DT 50 of dichlofluanid at pH 8.2 and 20°C is 1.2 hours. Therefore no long time exposure of marine organisms to dichlofluanid can be expected.</p> <p>In addition the rapid degradation of the active at high pH values causes problems with regard to the technical feasibility of the test. In the corresponding freshwater study the pH was already adjusted to about 7 to achieve a higher stability of the active (DT 50 at pH 7 and 20 °C = 19 hours. Due to the very low concentrations which has to be kept stable in a flow through test artefacts are likely to occur the more rapid the degradation would be.</p> <p>In addition according to TGD on marine risk assessment (2003) a study on marine fish will not improve the assessment factor if a study on freshwater fish is already available. This is because the sensitivity of marine and freshwater fishes is assumed to be not much different. This assumption is supported by acute fish data which are available for dichlofluanid on marine and freshwater fishes (see document IIA).</p> <p>Taking the above mentioned arguments into account (and in addition animal protection because it is a test on vertebrates) it is justified not to perform a test on reproduction and growth rate on a appropriate marine fish species.</p>	
Undertaking of intended data submission []	–	
Evaluation by Competent Authorities		
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	19/11/13	

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Evaluation of applicant's justification Conclusion Remarks	<p>The Technical Guidance Document of Risk Assessment (2003) states that in relation to differences between marine and freshwater aquatic organisms, no comparison of long-term effects data has been made due to the lack of suitable data but that there are no reasons to believe that a systemic bias to freshwater or marine species would exist. Therefore, it is proposed that data on freshwater or marine fish, crustacean and algae be used interchangeably for evaluation of the risks to either compartment.</p> <p>A PNEC_{water} for saltwater has been derived based on chronic freshwater studies, in line with TGD (2003) guidance. Additionally, acute studies with freshwater and marine fish species indicate similar sensitivities to dichlofluanid (Sheepshead minnow LC50 = 90.1 µg a.s./L while freshwater species LC50 = 10-120 µg a.s./L).</p> <p>The applicant's justification is accepted. No further data on the chronic toxicity of dichlofluanid to marine fish species is required.</p>
Date Evaluation of applicant's justification Conclusion Remarks	<p>COMMENTS FROM OTHER MEMBER STATE (<i>specify</i>)</p> <p><i>Give date of comments submitted</i></p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p><i>Discuss if deviating from view of rapporteur member state</i></p>