

<b>Section 7.4.3.3.2a/b</b> <b>Annex Point IIIA 13.2.3</b>	<b>Bioaccumulation in a appropriate freshwater or <u>marine</u> invertebrate species</b>	
<b>JUSTIFICATION FOR NON-SUBMISSION OF DATA</b>		Official use only
<b>Other existing data</b> [ ] <b>Limited exposure</b> [X]	<b>Technically not feasible</b> [X] <b>Scientifically unjustified</b> [X] <b>Other justification</b> [X].	
<b>Detailed justification:</b>	<p>A test on bioaccumulation in a appropriate freshwater or marine invertebrate species was not performed due to the following reasons:</p> <p>For PT 21 only this data requirement is only related to marine species, therefore no study on freshwater invertebrate species had to be performed.</p> <p>In seawater the active dichlofluanid is very rapidly hydrolysed and detoxified to DMSA (Dimethylaminosulfanilid, 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 in natural marine environments.</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. Due to the very low concentrations which have to be kept stable in a flow through test artefacts are likely to occur the more rapid the degradation would be.</p> <p>For freshwater a flow through test on bioaccumulation in fish is available with <sup>14</sup>C labelled active. Based on the uptake of the total radioactivity a BCF of 72 was obtained, which can be regarded as a worst case because not only the active is covered but also all metabolites and degradation products like DMSA. The BCF value is significantly below 100, which would trigger a bioaccumulation potential of concern.</p> <p>The degradation product DMSA has a log Pow of 1.59 which indicates that the compound has no relevant bioaccumulation potential.</p> <p>Taking the above mentioned arguments into account it is justified not to perform a test on bioaccumulation in a appropriate marine invertebrate species.</p>	
<b>Undertaking of intended data submission</b> [ ]	–	

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<b>Evaluation by Competent Authorities</b>	
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>	
<b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>	
<b>Date</b>	19/11/13
<b>Evaluation of applicant's justification</b>	The log Kow values of the active substance and main metabolite DMSA indicate a low potential for bioaccumulation. Additionally, a valid fish bioconcentration study confirms a low bioconcentration potential. No further consideration of bioaccumulation in aquatic organisms is necessary.
<b>Conclusion</b>	The applicant's justification is accepted. No further data on bioaccumulation in aquatic organisms are required.
<b>Remarks</b>	
<b>COMMENTS FROM OTHER MEMBER STATE</b> <i>(specify)</i>	
<b>Date</b>	<i>Give date of comments submitted</i>
<b>Evaluation of applicant's justification</b>	<i>Discuss if deviating from view of rapporteur member state</i>
<b>Conclusion</b>	<i>Discuss if deviating from view of rapporteur member state</i>
<b>Remarks</b>	