

Section A 7.1.1.2.2 Annex Point IIA VII.7.6.1.2	Inherent biodegradability		
JUSTIFICATION FOR NON-SUBMISSION OF DATA			Official use only
Other existing data [X]	Technically not feasible []	Scientifically unjustified []	
Limited exposure []	Other justification []		
Detailed justification:	<p>Based on the information obtained from the study described under Section A 7.1.1.2.1 (i.e. the a.i. is not readily biodegradable due to inhibitory effects to the activated sludge micro-organisms), it is considered that the a.i. is not likely to pass the test on inherent biodegradability either, and therefore this test has not been performed.</p> <p>Further higher tier simulation tests conducted under Sections A 7.1.2.2.1 and A 7.2.1 and A 7.2.2.1 showed rapid degradation and mineralisation of the a.i.</p>		
Undertaking of intended data submission []	Not applicable.		
Evaluation by Competent Authorities			
EVALUATION BY RAPPORTEUR MEMBER STATE			
Date	25 Nov 2009		
Evaluation of applicant's justification	Acceptable		
Conclusion	<p>Non submission of an inherent biodegradability is considered acceptable, due to the submission of a study on aerobic degradation in a sewage treatment plant. This allows the use of pre-adapted micro-organisms as in the inherent biodegradability test.</p> <p>As lower concentrations of active substance were not investigated during the ready biodegradability test, is not possible to say whether the inherent biodegradability test would have been passed or not. Attention is also drawn to the applicant's Doc IIA, section 4.1.1.1, which states, '[In the] ready biodegradability study... at lower concentrations degradation of OIT could be expected even under the very conservative conditions of a closed bottle test.' However as this was not formally tested it should be considered as only a speculative statement on behalf of the Applicant.</p>		
Remarks	The justification presented has been reviewed and accepted.		
COMMENTS FROM OTHER MEMBER STATE (<i>specify</i>)			

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Date

Evaluation of applicant's justification
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Conclusion

Remarks
