

Section A6	Other test(s) related to the exposure of humans	
Annex Point A6.14		
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [<input type="checkbox"/>]	Technically not feasible [<input type="checkbox"/>]	Scientifically unjustified [x]
Limited exposure [<input type="checkbox"/>]	Other justification [<input type="checkbox"/>]	
Detailed justification:	<p>According to the 'Technical Guidance Document on data requirements' this is an additional data requirement and under IIIA 6.14 the following is cited:</p> <ul style="list-style-type: none"> · Toxicity of degradation products, by-products and reaction products related to human exposure. · Information is required on the toxic effects of substances generated from an active substance, other than mammalian metabolites, in normal use of biocidal product. · The decision as to the need for this data should be made on case-by-case basis by expert judgement (see Chapter 1.2, point 4). Where human exposure is significant, toxicity testing may be needed. · This data may be relevant for many product types. As examples, product types 1 and 2 (reaction products with water when the substance is used for human hygiene purposes or reaction products with water or other materials released in water or air when the substance is used for the treatment of bathing waters), product type 5 (substances produced in a reaction with drinking water), product types 6, 7, 9 and 10 (residuals in treated materials), product type 8 (irritating and sensitising effects of chemical compounds, such as metal salts, developed on the surface of the treated wood) and product type 18 (products, which may produce harmful substances with water during gassing)." <p>Lactic acid is a naturally occurring substance in the human body and in human food, and is also authorized to be used as a food additive. As the exposure due to the use of biocidal products will not substantially contribute to the total systemic exposure, no tests related to the exposure of humans are deemed necessary. An expert statement on the role of lactic acid in the human body, as well as its presence in food (both naturally and as a food additive) is presented in A6.2-01.</p>	
Undertaking of intended data submission [<input type="checkbox"/>]	Not applicable	
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	2008/07/09	
Evaluation of applicant's justification	Applicant's justification is acceptable.	
Conclusion	Applicant's justification is acceptable.	

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Remarks	None
	COMMENTS FROM OTHER MEMBER STATE (<i>specify</i>)
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	