

<b>Section A6</b>	<b>Reproductive toxicity</b>	
<b>Annex Point A6.8</b>		
<b>JUSTIFICATION FOR NON-SUBMISSION OF DATA</b>		Official use only
<b>Other existing data</b> [ ]	<b>Technically not feasible</b> [ ]	<b>Scientifically unjustified</b> [x]
<b>Limited exposure</b> [ ]	<b>Other justification</b> [ ]	
<b>Detailed justification:</b>	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 studies on reproductive toxicity 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.	
<b>Undertaking of intended data submission</b> [ ]	Not applicable	
<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>	2008/07/08	
<b>Evaluation of applicant's justification</b>	Applicant's justification is acceptable. Furthermore, L-(+)-lactic acid is of very low systemic toxicity in mammals and the concentration of endogenous occurring lactic acid in the amniotic fluid (4.1-12.9 mM; 37-128 mg/100 mL, Sims et al. 1983; Hagenfeld & Hagenfeld 1972) is approx. 6 times higher than the concentration in maternal blood (8-17 mg/100 mL plasma; Doc. A6.6.1) in humans. Thus, it seems to be unlikely that lactic acid might bear a developmental toxicity potential. However, there is a publication available on developmental toxicity testing of lactic acid in mice (Colomina et al. 1992). In the absence of other data, this publication should be used as key study, a DocIII summary has to be submitted by the participant.	
<b>Conclusion</b>	Applicant's justification is acceptable.	
<b>Remarks</b>	None	
<b>COMMENTS FROM OTHER MEMBER STATE (specify)</b>		
<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>		

