

Section A6		Short-term repeated-dose toxicity	
Annex Point A6.3			
JUSTIFICATION FOR NON-SUBMISSION OF DATA			Official use only
Other existing data []	Technically not feasible []	Scientifically unjustified [x]	
Limited exposure []	Other justification []		
Detailed justification:	<p>According to the 'Technical Guidance Document on data requirements' these test are used as a range-finding test and are not required when an adequate sub-chronic toxicity is available in a rodent.</p> <p>For lactic acid, a 13-week oral sub-chronic toxicity study was performed in rats. Furthermore, a chronic toxicity/carcinogenicity study was performed in rats.</p> <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 further repeated-dose studies 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>		X
Undertaking of intended data submission []	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	2008/07/08		
Evaluation of applicant's justification	<p>The 13-week oral sub-chronic toxicity study and the chronic toxicity /carcinogenicity study were performed using calcium lactate and lack some detail (published literature). Furthermore, it is not clear from the data which effects are due to high calcium uptake and which might be due to lactic acid. Thus, the data are of low reliability and are only in part relevant for lactic acid.</p> <p>Nonetheless, in light of the low toxicity of lactic acid and the high endogenous exposure the applicant's justification is acceptable.</p>		
Conclusion	Applicant's justification is acceptable.		
Remarks	None		

Section A6 **Short-term repeated-dose toxicity****Annex Point A6.3****COMMENTS FROM OTHER MEMBER STATE** (*specify*)**Date***Give date of comments submitted***Evaluation of applicant's
justification***Discuss if deviating from view of rapporteur member state***Conclusion***Discuss if deviating from view of rapporteur member state***Remarks**