

Section A6	Carcinogenicity	
Annex Point A6.7		
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' carcinogenicity should be available in a rodent and one other mammalian species.</p> <p>For lactic acid, 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 carcinogenicity 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>	
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 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 the light of the low toxicity of lactic acid and the high endogenous exposure the applicant's justification for the missing study in a second species is acceptable.</p>	
Conclusion	Applicant's justification is acceptable.	
Remarks	None	

Section A6 Carcinogenicity**Annex Point A6.7****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**