

Section A6	Genotoxicity	
Annex Point A6.6		
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>The genotoxicity of lactic acid has been reviewed by the Cosmetic Ingredient Review Panel (CIR), the review is included in this dossier as a key study (A6.6.1-02). Furthermore, some <i>in vitro</i> genotoxicity studies are available in the literature, these have been summarized in the IUCLID.</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 genotoxicity 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	2008/07/09	
Evaluation of applicant's justification	Applicant's version is not acceptable. The applicant submitted <i>in vitro</i> genotoxicity data for which a DocIII document is missing.	
Conclusion	Applicant's justification is not acceptable. For the cited literature (Ishidate et al. 1984 and Al-Ani & Al-Lami 1988) DocIII Documents have to be submitted because these studies are regarded as key studies.	
Remarks	None	
COMMENTS FROM OTHER MEMBER STATE (specify)		
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		