

<b>Section A6</b>	<b>Mechanistic studies</b>	
<b>Annex Point A6.10</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>	<p>According to the 'Technical Guidance Document on data requirements' this is an additional data requirement and under IIIA 6.10 the following is cited:</p> <p>"Mechanistic study - any studies necessary to clarify effects reported in toxicity studies [Ann.IIIA, VI. 7.]</p> <ul style="list-style-type: none"> <li>· This data may be relevant on the basis of the toxicological properties of a substance.</li> <li>· Studies of the mechanisms of toxicity may be necessary when there are indications that active substance may have e.g. a non-genotoxic mechanism for carcinogenicity, species specific effects, adverse effects on reproduction, immunotoxicity or hormone related effects.</li> <li>· Scientific judgement is required to decide whether any supplementary studies are needed (see Chapter 1.2, point 4)."</li> </ul> <p>L(+) Lactic acid does not have specific effects as meant under this section. 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 studies on specific effects 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>	
<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>	2008/07/09	
<b>Evaluation of applicant's justification</b>	Applicant's justification is acceptable.	
<b>Conclusion</b>	Applicant's justification is acceptable.	
<b>Remarks</b>	None	
<b>COMMENTS FROM OTHER MEMBER STATE</b> ( <i>specify</i> )		
<b>Date</b>	<i>Give date of comments submitted</i>	

**Section A6****Mechanistic studies****Annex Point A6.10****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**