

Section A6		Neurotoxicity	
Annex Point A6.9			
		JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [x]	Technically not feasible []	Scientifically unjustified [x]	
Limited exposure []	Other justification []		
Detailed justification:	<p>According to the ‘Technical Guidance Document on data requirements’ this is an additional data requirement and under IIIA6.9 the following is cited:</p> <p>“Neurotoxicity study [Ann. IIIA, VI. 1.]</p> <ul style="list-style-type: none"> - This data may be relevant on the basis of the toxicological properties of a substance - Neurotoxicity studies detect functional changes and/or structural and biochemical changes in the central and peripheral nervous systems. These changes can be morphological, physiological (e.g. electroencephalographic changes), or behavioural nature, or can be changes in biochemical parameters (e.g. neurotransmitter levels). - If there are any indications that the active substance may have neurotoxic properties then specific neurotoxicity studies are required. Indications of neurotoxicity can be acquired from the standard systemic toxicity studies. Further investigation is possible using standard repeated dose toxicity tests with incorporation of specific neurotoxicity measures, like sensory activity, grip strength, and motor activity assessment (e.g. EC method B7 or the corresponding OECD guideline 407) and/or acute neurotoxicity testing using the OECD method 424. Expert judgement is required to decide whether a repeated dose neurotoxicity study is needed (see Chapter 1.2, point 4). - These studies have to be performed for substances of similar or related structures to those capable of inducing delayed neurotoxicity. If anticholinesterase activity is detected a test for response to reactivating agent may be required.” <p>Lactic acid is not expected to cause delayed neurotoxicity, as it does not have a similar or related structure of those capable of inducing delayed neurotoxicity. Furthermore, 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 neurotoxicity 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		

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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	Applicant's justification is acceptable.
Conclusion	Applicant's justification is acceptable.
Remarks	None
COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i>	
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	