

Section A6	Toxic effects on livestock and pets	
Annex Point A6.13		
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [<input type="checkbox"/>]	Technically not feasible [<input type="checkbox"/>]	Scientifically unjustified [x]
Limited exposure [<input type="checkbox"/>]	Other justification [<input type="checkbox"/>]	
Detailed justification:	<p>According to the 'Technical Guidance Document on data requirements' this is an additional data requirement and under IIIA 6.13 the following is cited:</p> <p>“An estimation on toxic effects and exposure via different exposure routes (e.g. inhalation, licking, skin contact and ingestion of poisoned bait) and in relevant, but exceptional cases, toxicity testing in livestock and pets is required. Toxic effects for livestock and pets should to be estimated or studied if the substance is to be used in spaces in which animals are housed, kept or transported or exposure is possible via drinking water or feedingstuffs.</p> <p>Information on lethal doses for different species, symptoms of poisoning, details of the time courses in case of poisoning and antidotes should also be submitted, if available.</p> <p>· This data may be relevant e.g. for product type 3 (substances used for veterinary hygiene purposes), product type 4 (disinfection of surfaces and equipment), product type 5 (drinking water) product types 8 and 10 (treated materials in areas in which animals are housed, kept or transported), product types 14, 15 and 23 (ingestion of baits), product types 16 and 17 (contaminated drinking water), product types 18 and 19 (repellents to be used for veterinary hygiene purposes).</p> <p>An expert judgement is required to decide whether any studies are needed (see Chapter 1.2, point 4).</p> <p>· This data is usually not required for the product types 1, 2, 6, 7, 9, 11, 12, 13, 20, 21 and 22.”</p> <p>Lactic acid is a naturally occurring substance in all living organisms, which also occurs in food. As the exposure due to the use of biocidal products will not substantially contribute to the total systemic exposure, no toxic effects on livestock and pets are expected. An expert statement on the role of lactic acid in mammals, as well as its presence in food is presented in A6.2-01.</p>	
Undertaking of intended data submission [<input type="checkbox"/>]	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	2008/11/10	

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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	