Purac Biochem

L(+) Lactic Acid

July/2007

Section A6	Food and feedingstuffs	
Annex Point A6.15		
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data []	Technically not feasible [] Scientifically unjustified [x]	
Limited exposure []	Other justification []	
Detailed justification:	This point covers 6.15.1 to 6.15.6 ! According to the 'Technical Guidance Document on data requirements' this is an additional data requirement and under IIIA 6.15 the following is cited: "If the active substance is to be used in preparations for use where food for human consumption is prepared, consumed or stored, or where feedingstuff for livestock is prepared, consumed or stored, the tests and results in accordance with paragraphs A6.15.1-6.15.5. shall be required." 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 data on food and feedingstuffs 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.	
Undertaking of intended data submission []	Not applicable	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2016/12/12	
Evaluation of applicant's justification	PT 2 uses As the active substance of the representative (dummy) biocidal product, la is intended to be used as a disinfecting liquid handsoap that is rinsed off th after a short contact time. No contact with food or drinking water occurs. PT 3 and PT 4 uses Lactic acid naturally occurs in various foods such as fruits, fermented dair products, fermented vegetables, beer and wine. In addition lactic acid is an approved food additive in the EU (E270) and may be used therapeutically veterinary medicinal products (e.g. in teat dips). Residues in food from the intended PT 3 (disinfectant for udders of dairy of and PT 4 (disinfectant for brewery installations) uses of lactic acid are explicit low compared to naturally occurring levels in food. Therefore, the interfuses do not significantly contribute to consumer exposure to lactic acid. M. lactic acid is permanently present in the human body as it is an endogenous process.	y n in cows) pected to nded loreover

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Conclusion	Submission of data on food and feedingstuffs is not required.
Remarks	None
	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	