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|---|--|---|-------------------|
| Section A6 | Medical data in anonymous form | | |
| Annex Point A6.12 | | | |
| JUSTIFICATION FOR NON-SUBMISSION OF DATA | | | Official use only |
| Other existing data [<input type="checkbox"/>] | Technically not feasible [<input type="checkbox"/>] | Scientifically unjustified [<input checked="" type="checkbox"/>] | |
| Limited exposure [<input type="checkbox"/>] | Other justification [<input type="checkbox"/>] | | |
| Detailed justification: | <p>This statement covers 6.12.1 to 6.12.8 ! According to the 'Technical Guidance Document on data requirements' under IIIA 6.12 the following is cited:</p> <p>“Medical data in anonymous form [Ann IIA, VI. 6.9.]</p> <ul style="list-style-type: none"> • Data and information on the effects of human exposure, <u>if available</u>, may provide valuable information for confirming the validity of extrapolations made and conclusions reached from animal data and for identifying unexpected adverse effects which are specific to humans. • Data and information following accidental or occupational exposure have to be submitted <u>where available</u> and of adequate quality. Practical data and information relevant to the recognition of the symptoms of poisoning, on the effectiveness of first aid and therapeutic measures must be included. • It is usually not possible to require this data for new active substances.” <p>Thus, the information under 6.12 should be provided <u>if available</u>; if no information is available, there is no need to justify this further.</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 medical data 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 [<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 | 2008-06-30 | | |

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| Evaluation of applicant's justification | Justification is acceptable with restriction (see remarks) | There is a publication on a fatal lactic acid poisoning available. This publication was introduced by the RMS (Fühner, 1934; cf CA-Table 1 for details). Since the participant has a long history and experience in the production, packaging and shipping of L(+) lactic acid it can be assumed that there are medical records available of the workers working in the plants of the participant. These data have to be included in the dossier. There are also data on skin irritation in humans available (York et al. 1996) which should be used as a key study in the skin irritation/corrosion part. | |
| Conclusion | Applicant's version is acceptable (see remarks). Lactic acid is a physiological part of human metabolism and occurs in food. | The applicant's justification is acceptable with the following amendment: A publication on a fatal lactic acid poisoning is available (cf CA- Table 1 for details). Since the participant has a long history and experience in the production, packaging and shipping of L(+) lactic acid, so it can be assumed that there are medical records of the workers working in the plants of the participant are available. These data have to be included in the dossier. | |
| Remarks | As exposure to lactic acid during the manufacturing process could differ in route and amount from background levels, medical surveillance data on personnel working in the applicant's plant should be provided for reason of completeness. | | |
| 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 | | | |

CA-Table 1:

| Kind of study (e.g. case reports) | Examination methods, number of individuals examined | Results | References |
|--|--|--|--|
| Case report, fatal poisoning (accidental exposure to ca. 33 g lactic acid by stomach tube) | Clinical observation, (histo-)pathology, tissue distribution of lactic acid; 1 F | Pain, vomiting, gastrointestinal necrosis, haemorrhages and bleeding, death within 12 h, 4 d p.m.: from analysis of lactic acid content in different organs an estimate of 17 g lactic acid is given, mainly in the gastrointestinal tract and brain | Fühner H 1932, Arch Toxicol 3(1):71-74 |