

**Section A6.1.4****Acute Dermal Irritation****Annex Point IIA6.4***Pigs*Official  
use only**1 REFERENCE**

- 1.1 Reference** [REDACTED] (1987). Acute dermal irritation/corrosion study with lactic acid (88%) in pigs. TNO report nr. V87/405/270419. GLP, unpublished.
- 1.2 Data protection** Yes
- 1.2.1 Data owner Purac Biochem BV
- 1.2.2 Companies with letter of access No
- 1.2.3 Criteria for data protection Data submitted to the MS after 13 May 2000 on existing [a.s. / b.p.] for the purpose of its entry into Annex I

**2 GUIDELINES AND QUALITY ASSURANCE**

- 2.1 Guideline study** Yes, OECD 404 / EEC B4
- 2.2 GLP** Yes
- 2.3 Deviations** Pigs were used, as pigs are more appropriate test animals than rabbits (normally used for skin irritation tests). A detailed justification is included in the report.

**3 MATERIALS AND METHODS**

*In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.*

- 3.1 Test material** As given in section 2 (88% lactic acid)
- 3.1.1 Lot/Batch number USP, batch U198
- 3.1.2 Specification As given in section 2
- 3.1.2.1 Description** Clear colourless liquid
- 3.1.2.2 Purity** 88 %
- 3.1.2.3 Stability** As given in section 2
- 3.2 Test Animals**
- 3.2.1 Species Pigs
- 3.2.2 Strain Not applicable
- 3.2.3 Source F1 from Large White (GY) x Dutch Landrace (NL), born on 25-11-1986 and bred in the test laboratory
- 3.2.4 Sex Male
- 3.2.5 Age/weight at study initiation 40-50 kg
- 3.2.6 Number of animals per group 3
- 3.2.7 Control animals no

**Section A6.1.4 Acute Dermal Irritation****Annex Point IIA6.4***Pigs*

|   |   |
|---|---|
| <b>3.3 Administration/ Exposure</b>                   | Dermal  |
| 3.3.1 Application                                     |   |
| <b>3.3.1.1 Preparation of test substance</b>          | Test substance was used as delivered.   |
| <b>3.3.1.2 Test site and Preparation of Test Site</b> | Three separate areas of shaved dorsal skin  |
| 3.3.2 Occlusion                                       | Occlusive patch   |
| 3.3.3 Vehicle   | Not applicable  |
| 3.3.4 Concentration in vehicle                        | Not applicable  |
| 3.3.5 Total volume applied                            | 0.5 ml test material per application site   |
| 3.3.6 Removal of test substance                       | Lukewarm water  |
| 3.3.7 Duration of exposure                            | Three exposure periods for different application sites: 3 minutes, 60 minutes and 4 hours |
| 3.3.8 Post exposure period                            | 21 days   |
| 3.3.9 Controls  | No  |
| <b>3.4 Examinations</b>                               |   |
| 3.4.1 Clinical signs                                  | No  |
| 3.4.2 Dermal examination                              | Yes   |
| <b>3.4.2.1 Scoring system</b>                         | Draize et al  |
| <b>3.4.2.2 Examination time points</b>                | 1 day, 2, 3, 7, 14 and 21 days  |
| Other examinations                                    | Not applicable  |
| <b>3.5 Further remarks</b>                            |   |
| <b>RESULTS AND DISCUSSION</b>                         |   |
| <b>3.6 Average score</b>                              |   |
| 3.6.1 Erythema  | 0   |
| 3.6.2 Edema   | 0   |
| <b>3.7 Reversibility</b>                              | Not applicable  |

**Section A6.1.4****Acute Dermal Irritation****Annex Point IIA6.4***Pigs*

|   |   |   |
|---|---|---|
| <b>3.8 Other examinations</b>               | Some minor superficial wounds and one day later small crusts were observed at application site and non-treated skin areas in two pigs. This effect was not considered treatment related as it also occurred at non-treated skin. These minor injuries were probably caused by shaving along the walls or floor of the stable. |   |
| <b>3.9 Overall result</b>                   | No dermal irritation responses related to treatment with lactic acid were observed.   |   |
| <b>4 APPLICANT'S SUMMARY AND CONCLUSION</b> |   |   |
| <b>4.1 Materials and methods</b>            | Skin irritation was tested according to OECD 404 on three pigs  |   |
| <b>4.2 Results and discussion</b>           | No dermal irritation responses related to treatment with lactic acid were observed.   |   |
| <b>4.3 Conclusion</b>                       | Lactic acid is not considered irritating or corrosive to skin.  | X |
| 4.3.1 Reliability                           | 1   |   |
| 4.3.2 Deficiencies                          | No  |   |

**Evaluation by Competent Authorities**

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

**EVALUATION BY RAPPORTEUR MEMBER STATE**

|                               |   |
|-------------------------------|---|
| <b>Date</b>                   | 2008/07/16  |
| <b>Materials and Methods</b>  | Applicant's version is acceptable.  |
| <b>Results and discussion</b> | Applicant's version is acceptable.  |
| <b>Conclusion</b>             | 4.3 Under the conditions tested lactic acid was not irritant or corrosive to pig skin.  |
| <b>Reliability</b>            | 1   |
| <b>Acceptability</b>          | Acceptable without restrictions   |
| <b>Remarks</b>                | L(+) lactic acid proved to be corrosive in <i>in vitro</i> and rabbit dermal irritation tests and irritating in human patch tests (York et al. 1996). The participant proposed classification as R38. Since this study does not support the classification with R38, it doesn't seem to be adequate to use this study as sole dermal irritation key study (as proposed by the participant) to provide information on the irritating properties of L(+) lactic acid. |

**COMMENTS FROM ...**

|                               |   |
|-------------------------------|---|
| <b>Date</b>                   | <i>Give date of comments submitted</i>  |
| <b>Materials and Methods</b>  | <i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.<br/>Discuss if deviating from view of rapporteur member state</i> |
| <b>Results and discussion</b> | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Conclusion</b>             | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Reliability</b>            | <i>Discuss if deviating from view of rapporteur member state</i>  |

**Section A6.1.4**

**Acute Dermal Irritation**

**Annex Point IIA6.4**

*Pigs*

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**Acceptability**

*Discuss if deviating from view of rapporteur member state*

**Remarks**

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