

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. [REDACTED]. GLP, unpublished.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

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3.3 Administration/ Exposure	Dermal
3.3.1 Application	
3.3.1.1 Preparation of test substance	Test substance was used as delivered.
3.3.1.2 Test site and Preparation of Test Site	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
3.4 Examinations	
3.4.1 Clinical signs	No
3.4.2 Dermal examination	Yes
3.4.2.1 Scoring system	Draize et al
3.4.2.2 Examination time points	1 day, 2, 3, 7, 14 and 21 days
Other examinations	Not applicable
3.5 Further remarks	
RESULTS AND DISCUSSION	
3.6 Average score	
3.6.1 Erythema	0
3.6.2 Edema	0
3.7 Reversibility	Not applicable

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3.8	Other examinations	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.	
3.9	Overall result	No dermal irritation responses related to treatment with lactic acid were observed.	
4 APPLICANT'S SUMMARY AND CONCLUSION			
4.1	Materials and methods	Skin irritation was tested according to OECD 404 on three pigs	
4.2	Results and discussion	No dermal irritation responses related to treatment with lactic acid were observed.	
4.3	Conclusion	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	
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	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
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EVALUATION BY RAPPORTEUR MEMBER STATE	
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Date	2008/07/16
Materials and Methods	Applicant's version is acceptable.
Results and discussion	Applicant's version is acceptable.
Conclusion	4.3 Under the conditions tested lactic acid was not irritant or corrosive to pig skin.
Reliability	1
Acceptability	Acceptable without restrictions
Remarks	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 ...	
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Date	<i>Give date of comments submitted</i>
Materials and Methods	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>

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Acceptability

Discuss if deviating from view of rapporteur member state

Remarks
