

**Section A6.1.4 Acute Dermal Irritation****Annex Point IIA6.4***Rabbits*Official  
use only

		<b>1 REFERENCE</b>
<b>1.1 Reference</b>		██████████ (1995) Acute dermal irritation/corrosion study with a 10% aqueous solution of lactic acid in albino rabbits TNO report V95.387 GLP, unpublished
<b>1.2 Data protection</b>		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
		<b>2 GUIDELINES AND QUALITY ASSURANCE</b>
<b>2.1 Guideline study</b>		Yes, OECD 404 / EEC B4
<b>2.2 GLP</b>		Yes
<b>2.3 Deviations</b>		No
		<b>3 MATERIALS AND METHODS</b>
<b>3.1 Test material</b>		10% aqueous solution of lactic acid
3.1.1 Lot/Batch number		JVR-NAL-21
3.1.2 Specification		Clear, colourless liquid
<b>3.1.2.1 Description</b>		
<b>3.1.2.2 Purity</b>		10%
<b>3.1.2.3 Stability</b>		Not mentioned (storage conditions: ambient)
<b>3.2 Test Animals</b>		
3.2.1 Species		Rabbit
3.2.2 Strain		SPF bred New Zealand White albino
3.2.3 Source		Broekman Institute, Someren, The Netherlands
3.2.4 Sex		Male
3.2.5 Age/weight at study initiation		Young adults (2000-2470 kg at start of the study))
3.2.6 Number of animals per group		3
3.2.7 Control animals		no
<b>3.3 Administration/ Exposure</b>		Dermal
3.3.1 Application		

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<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>	Skin site in clipped back and flanks of the animal
3.3.2 Occlusion	Semi-occlusive
3.3.3 Vehicle	No vehicle, test substance was used as delivered.
3.3.4 Concentration in vehicle	Not applicable
3.3.5 Total volume applied	0.5 ml test material per patch per application site
3.3.6 Removal of test substance	Moistened tissue
3.3.7 Duration of exposure	4-hour exposure
3.3.8 Post exposure period	72 hours
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 (J. Pharmacol. Exp. Ther. 82 (1944), pp 377-390)
<b>3.4.2.2 Examination time points</b>	1, 24, 48, 72 hours after treatment
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
<b>3.8 Other examinations</b>	No
<b>3.9 Overall result</b>	A 10% aqueous solution of lactic acid, when buffered at pH 4.0, is not irritating for the skin of rabbits after a 4-hour dermal contact period..

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<b>4.1</b>	<b>Materials and methods</b>	Skin irritation was tested according to OECD 404 on three New Zealand White albino rabbits
<b>4.2</b>	<b>Results and discussion</b>	No dermal irritation responses related to treatment with lactic acid were observed.
<b>4.3</b>	<b>Conclusion</b>	Lactic acid is not irritating or corrosive to skin.
4.3.1	Reliability	1
4.3.2	Deficiencies	No

X

**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>	2008/12/18
<b>Materials and Methods</b>	Applicant's version is acceptable.
<b>Results and discussion</b>	Applicant's version is acceptable.
<b>Conclusion</b>	A 10 % aqueous solution of lactic acid, when buffered at pH 4.0, is not irritating for the skin of rabbits after a 4-hour dermal contact period.
<b>Reliability</b>	1
<b>Acceptability</b>	Acceptable
<b>Remarks</b>	None

**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. 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>
<b>Acceptability</b>	<i>Discuss if deviating from view of rapporteur member state</i>
<b>Remarks</b>	