

Section A4.2**Analytical Methods for Detection and Identification****Annex Point IIA4.1/4.2 & IIIA-IV.1**


		1 REFERENCE	
1.1 Reference		Klein, J. (2007)	
		Lactic acid in earth	
		Purac Document no. AMENV001	
		Not GLP, Unpublished	
1.2 Data protection		Yes	
1.2.1 Data owner		Purac Biochem	
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/IA / authorisation]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study		Internal method	
2.2 GLP		No	
2.3 Deviations		Not applicable	
		3 MATERIALS AND METHODS	
3.1 Preliminary treatment			
3.1.1 Enrichment		Not applicable	
3.1.2 Cleanup		Not applicable	
3.2 Detection			
3.2.1 Separation method		[REDACTED]	
3.2.2 Detector		[REDACTED]	
3.2.3 Standard(s)		Lactic acid standard solution	
3.2.4 Interfering substance(s)		Not applicable	
3.3 Linearity			
3.3.1 Calibration range		4.9-32.3 mg/g soil	
3.3.2 Number of measurements		8	
3.3.3 Linearity		Not mentioned	
3.4 Specificity: interfering substances		Not applicable	

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3.5	Recovery rates at different levels	88-101%
3.5.1	Relative standard deviation	Not mentioned
3.6	Limit of determination	Not mentioned
3.7	Precision	
3.7.1	Repeatability	Not mentioned
3.7.2	Independent laboratory validation	Not mentioned

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1	Materials and methods	
4.2	Conclusion	The method shows a recovery rate of 88-101% and is suitable for determining lactic acid in soil samples.
4.2.1	Reliability	2
4.2.2	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

Date	2014/06/23
Materials and methods	The acceptability of the method of Klein /2007 cannot be judged because fundamental validation data are missing.
Conclusion	No relevant residues of L(+) lactic acid in soil are expected. Analytical methods for L(+) lactic acid in soil are not required.
Reliability	4
Acceptability	not acceptable
Remarks	none

COMMENTS FROM ...

Date	<i>Give date of comments submitted</i>
Results and discussion	<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>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>

Section A4.2

Analytical Methods for Detection and Identification

**Annex Point II A4.1/4.2 &
III A-IV.1**

Reliability

Discuss if deviating from view of rapporteur member state

Acceptability

Discuss if deviating from view of rapporteur member state

Remarks
