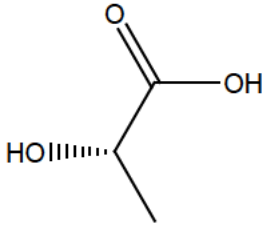


Section A2

Identity of Active Substance

Subsection (Annex Point)		Official use only
2.1	Common name (IIA2.1) L(+) Lactic acid (See Document IVA2-02 and IVA2-03, included in the confidential part)	x
2.2	Chemical name (IIA2.2) (S)-2-hydroxypropanoic acid	x
2.3	Manufacturer's development code number(s) (IIA2.3) PURAC SY-83 (See Document IVA2-01, included in the confidential part)	
2.4	CAS No and EC numbers (IIA2.4)	
2.4.1	CAS-No 79-33-4	
2.4.2	EC-No 201-196-2	
2.4.3	Other Not applicable	
2.5	Molecular and structural formula, molecular mass (IIA2.5)	
2.5.1	Molecular formula C ₃ H ₆ O ₃	
2.5.2	Structural formula  (S)-2-hydroxypropanoic acid ₁	
2.5.3	Molecular mass 90.08 g/mol	
2.6	Method of manufacture of the active substance (IIA2.1) See Document III_A 2.6 in the confidential part of the dossier.	x
2.7	Specification of the purity of the active substance, as appropriate (IIA2.7) g/kg g/l % w/w % v/v L(+)-lactic acid: lower limit 92.95 mean 93.5 upper limit 94.04 Based on Doc IV, A2_02, as submitted on 14-02-2008	
2.8	Identity of impurities and additives, as appropriate (IIA2.8) Impurities and identity of impurities are included as separate formats (A2.8) for each impurity in the confidential part.	
2.8.1	Isomeric composition Stereochemical purity of lactic acid in the 93% aqueous solution: ≥99% L(+) lactic acid and < 1% D(-) lactic acid.	

Section A2

Identity of Active Substance

2.9 The origin of the natural active substance or the precursor(s) of the active substance (IIA2.9)

Metabolic substance in all living cells



Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2016/03/29
Materials and methods	
Conclusion	
Reliability	
Acceptability	
Remarks	The information on purity of L (+) Lactic acid given in this document is based on the initially submitted data from 2008. In order to make the whole dossier more comprehensible the corresponding information are kept in the documents. Due to the fact that with the BPR a five batch analysis is requested and L (+) Lactic is manufactured at 5 sites we requested the corresponding data from the applicant. For the results of the 5 batch analyses, which build the base of the final specification of L (+) Lactic acid, please refer to section 1.3 of the confidential Doc II A.
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2009/03/01
Materials and methods	The correct quotation of the following filed entries is: 2.1 Common name : L(+) Lactic acid, the additional details to Document IV are not necessary 2.2 Chemical name: (S)-2-Hydroxypropanoic acid (IUPAC) Propanoic acid, 2-hydroxy-, (2S)- (CAS) 2.6 The existence of an equilibrium system is added in the confidential part A2.
Conclusion	The revised version is included
Reliability	1
Acceptability	acceptable
Remarks	
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>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	
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>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	