Table 1

Section A3 **Physical and Chemical Properties of Active Substance (LACTIC ACID 93% SOLUTION IN WATER)**

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.1 Melting point, boiling point, relative density (IIA3.1)								
3.1.1 Melting point	Not mentioned	Pure, crystalline solid lactic acid	53.0°C	The melting point of pure crystalline lactic acid was determined.	N		A3.1.1-01 Van Dongen (2006a)	3.1.1.a

Section A3 **Physical and Chemical Properties of Active Substance (LACTIC ACID 93% SOLUTION IN WATER)**

Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results** Give also data on test pressure, temperature, pH and concentration range if necessary	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
	Not mentioned	93%		[redacted]. No 'freezing' of the mixture will occur.	N		A3.5-01 Van Dongen (2007a)	3.1.1.b

Section A3 **Physical and Chemical Properties of Active Substance (LACTIC ACID 93% SOLUTION IN WATER)**

Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results** Give also data on test pressure, temperature, pH and concentration range if necessary	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
				[redacted]			A3.1.1-02	

Section A3 **Physical and Chemical Properties of Active Substance (LACTIC ACID 93% SOLUTION IN WATER)**

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
				The effect of increasing viscosity of highly concentrated solutions on the propensity of such solutions to stay supercooled instead of freezing or separating into their solid constituting components is a.o. supported by the work of Slama and Kodejs (1979). They conclude that if a solution has a viscosity at the liquidus temperature of ≥ 10 mPa.s, it can be supercooled. 93% lactic acid has a viscosity of 930 mPa.s at 0 °C, thus indicating that it is almost unavoidable that, with increasing viscosity at lowering the temperature, it will only stay supercooled, and will not solidify in any way.			A3.1.1_03 Slama and Kodejs (1979)	

Section A3 **Physical and Chemical Properties of Active Substance (LACTIC ACID 93% SOLUTION IN WATER)**

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.1.2 Boiling point	Not mentioned	88% 93%	**result:** 122 ° C **pressure:** 1.013 hPa **Not provided**	It is not possible to give one single boiling point for L(+) lactic acid. [redacted]	N		A3.1.2-01 Van Dongen (2006b)	3.1.2.a

Section A3 **Physical and Chemical Properties of Active Substance (LACTIC ACID 93% SOLUTION IN WATER)**

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.1.3 Bulk density/ relative density	Not mentioned	Pure lactic acid	**result:** >200 ° C **pressure:** 1.013 hPa	The boiling point of pure lactic acid is difficult to determine.	N		A3.1.2-01 Van Dongen (2006b)	3.1.2.b

Section A3 **Physical and Chemical Properties of Active Substance (LACTIC ACID 93% SOLUTION IN WATER)**

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
Bulk/rel. density 1	Not mentioned	[redacted] 93.0% @ 25°C	[redacted] 1.2130	Holten (1971) gives at page 23 a table with densities of aqueous solutions of lactic acid at different temperatures and concentrations. These data were used for a regression of the density as function of temperature and concentration. The result for an aqueous solution of lactic acid with a concentration of 93% w/w at 20°C is a density of 1.213 g/cm3 at 20°C. z = a + bx + cy a = 1.020 b = 0.00222 c = -0.000695 in which: z = density g/cm3 x = concentration % w/w y = temperature °C	N		A3.1.3-01 Van Dongen (2006c)	3.1.3

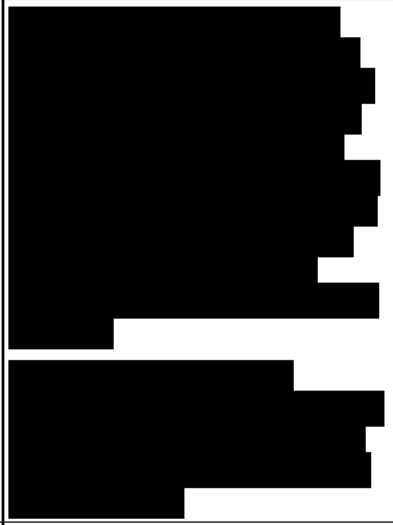
Section A3 **Physical and Chemical Properties of Active Substance (LACTIC ACID 93% SOLUTION IN WATER)**

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.2 Vapour pressure (IIA3.2)	Joback method Modified Grain Method	100%	**temperature:** 20 °C **result:** 0.0041 mbar	The atmospheric boiling point of monomeric lactic acid cannot be determined experimentally. It can however be estimated. The Joback group contribution method (Joback K.G., Reid R.C., "Estimation of Pure-Component Properties from Group-Contributions", Chem.Eng.Commun., 57, 233-243, 1987) predicts a boiling point of 508 K for lactic acid, based on a boiling point of 453 K for 2-chloropropionic acid and group contributions of 38.13 K and 92.88 K for chlorine and hydroxyl groups respectively. Using an estimated enthalpy of vaporization of 40 kJ/mol, the Clausius-Clapeyron equation predicts a vapour pressure for the subcooled liquid at ambient pressure and temperature of 9.5e-4 atm. The modified Grain group contribution method predicts an ambient vapour pressure of 3.7e-5 atm.	N		A3.2-01 Van Dongen (2006d) A3.2.1-03	3.2.a

Section A3 **Physical and Chemical Properties of Active Substance (LACTIC ACID 93% SOLUTION IN WATER)**

Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results** Give also data on test pressure, temperature, pH and concentration range if necessary	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
	Calculation	93%	**6.701 mbar @ 20°C**	[redacted]			A3.2-02 Nanninga (2008)	3.2.b

Section A3 **Physical and Chemical Properties of Active Substance (LACTIC ACID 93% SOLUTION IN WATER)**

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
								
3.2.1 Henry´s Law Constant (Pt. I-A3.2)	EPIWIN calculation	100%	**calculated: result: 1.13 E-7 atm-m^3/mole (bond contribution method) 3.39 E-9 atm-m3/mole (from estimated solubility and vapour pressure)**	Henry's law constant was estimated for pure L(+) lactic acid. Details in A3.2.1-03. For Pv/Saq method, Pv was 0.0286 mm Hg (estimated, modified Grain method) and Saq was 1E+006 mg/L (estimated: miscible).	N		A3.2.1-03 US-EPA (2008)	3.2.1

Section A3 **Physical and Chemical Properties of Active Substance (LACTIC ACID 93% SOLUTION IN WATER)**

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.3 Appearance (IIA3.3)								
3.3.1 Physical state	In-house method		Aqueous solution 88% (w/w)	Appearance of a 93% solution in indistinguishable from the appearance of an 88% solution.			A3.3-01	3.3.1
3.3.2 Colour	In-house method		≤ 100 Apha					3.3.2
3.3.3 Odour	In-house method		Not applicable					3.3.3
3.4 Absorption spectra (IIA3.4) **UV/VIS**		neat	UV/VIS spectra are included in Holten (1971). Maximum absorption is found at 210 nm				A3.4-02 Holten (1971b)	3.4.b UV

Section A3 **Physical and Chemical Properties of Active Substance (LACTIC ACID 93% SOLUTION IN WATER)**

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
		0.12%	Maximum absorption is found at 210 nm (water absorption	A3.4_02 contains a review of the UV absorption behaviour of lactic acid. This clearly shows that at wavelengths from 250 nm down to 210 nm, the absorbance of lactic acid steadily increases. Wavelengths <210 nm are irrelevant in nature; they are also irrelevant since at these wavelengths the absorbance of water will always dominate the UV absorption of aqueous solutions. A UV spectrum of a more dilute solution of lactic acid would therefore not be qualitatively different from the spectrum supplied in Document IV A3.4_04. Taken together, Documents IV A3.4_02 and _04 completely define the UV absorption behaviour of lactic acid in aqueous solution. The spectrum in Document IV A3.4-05 confirms this.			A3.4.-05 Lieuwen (2008)	3.4a UV

Section A3 **Physical and Chemical Properties of Active Substance (LACTIC ACID 93% SOLUTION IN WATER)**

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
IR			IR spectra are included in the expert statement	O-H (alcohol) stretching; 3600 cm^{-1} C-H stretching; 3000 cm^{-1} O-H (acid) stretching; 2900 cm^{-1} C=O stretching; 1800 cm^{-1}	N		A3.4-01 Van Dongen (2006f) A3.4-04 Van Dongen (2007)	3.4 IR
NMR			NMR spectra of crystalline and 90% lactic acid are included in Holten (1971).	Water as a solvent is incompatible with NMR spectroscopy. Therefore, it is not useful to try and take an NMR spectrum of 93% aqueous solution of lactic acid. [redacted]			A3.4-03 Holten (1971c)	3.4 NMR

Section A3 **Physical and Chemical Properties of Active Substance (LACTIC ACID 93% SOLUTION IN WATER)**

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
MS			An MS spectrum for the pure compound is included in the expert statement		N		A3.4-01 Van Dongen (2006f)	3.4 MS
			A GC-MS run is included for the 93% solution	This gives a GC chromatogram for the two main components, viz lactic acid and lactoyllactic acid (the dimer). MS spectra for both components are included. The spectrum for lactic acid is identical to that of the pure substance, with no Mother ion and a dominating peak at m/z 45 containing 2 oxygens (COOH+). The spectrum for lactoyl lactic acid also shows no Mother ion. The first non-negligible peak is for the lactoyl moiety at m/z 89. Major peaks are COOH+ at m/z 45, and possibly $C_2H_2O_3$, at m/z 74.	N		A3.4.-05 Lieuwen (2008)	3.4 MS

Section A3 **Physical and Chemical Properties of Active Substance (LACTIC ACID 93% SOLUTION IN WATER)**

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.5 Solubility in water (IIA3.5)		100%	86.1% lactic acid at 20°C	At 20°C, the solubility of monomeric lactic acid in water is 86.1%; the total concentration of lactic acid then is in the range of 94%.	N		A3.5-01 Van Dongen (2007a)	3.5.a
		93%	miscible	A lactic acid solution of any concentration up to at least 100%, at chemical equilibrium is fully miscible with water. Lactic acid solutions of low concentration are concentrated by evaporation of water at elevated temperature and reduced pressure. During evaporation to any concentration up to 100% no phase separation, solid/liquid or liquid/liquid, occurs during either the concentration step itself, or at cooling to room temperature (or below) after having reached chemical equilibrium (see also 3.1.1).			A3.5-01 Van Dongen (2007a)	3.5.b
3.6 Dissociation constant (-)	Calculated		pKa=3.85		N		A3.6-01 Van Dongen (2007b)	3.6

Section A3 **Physical and Chemical Properties of Active Substance (LACTIC ACID 93% SOLUTION IN WATER)**

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.7 Solubility in organic solvents, including the effect of temperature on solubility (IIIA3.1)	Methanol 2-ethylhexanol	Crystals Crystals	**result:** 78.6 % wt **temperature:** 20°C **result:** 29 % wt **temperature:** 20°C		N		A3.7-01 Van Dongen (2007a)	3.7
3.8 Stability in organic solvents used in b.p. and identity of relevant breakdown products (IIIA3.2)				Not required according to the Technical Notes for Guidance on Data requirements, as the products do not contain organic solvents.				

Section A3 **Physical and Chemical Properties of Active Substance (LACTIC ACID 93% SOLUTION IN WATER)**

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.9 Partition coefficient n-octanol/water (IIA3.6)	Shake-flask method.	Crystalline	**Log Kow = -.074**	[redacted] confirmed in literature, logPo/w = -0.72. [redacted]	N		A3.9-05 Van Lieshout (1997) A3.9-06 Nanninga (2003)	3.9a

Section A3 Physical and Chemical Properties of Active Substance (LACTIC ACID 93% SOLUTION IN WATER)

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
	Several methods.	[redacted]	[redacted]	[redacted]	N		[redacted]	3.9b
3.10 Thermal stability, identity of relevant breakdown products (IIA3.7)		Lactic acid 80%	≥ 5 years when stored at ambient conditions				A3.10-01 Van Dongen (2007d)	3.10a
	In-house method, stability tested at 25 and 40°C up to 5 years	Lactic Acid 90 and 80%	Storage stability is ≥ 5 years at 25 and 40°C, for both concentrations		N	1	A3.10-03 Van Dongen (2007g)	3.10b

Section A3 Physical and Chemical Properties of Active Substance (LACTIC ACID 93% SOLUTION IN WATER)

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.11 Flammability, including auto-flammability and identity of combustion products (IIA3.8)			Not applicable, product is an aqueous solution	From the structural formula and composition of the substance it can be concluded that the substance does not evolve any flammable gases in contact with water or humid air and that the substance is stable at room temperature in air and is not pyrophoric. A solution of lactic acid is as combustible as a sucrose solution of the same strengths. The determination of the flash point of an aqueous solution of lactic acid (90%) failed. When heated to 130°C the vapour still could not be ignited. (ISL FP93 5G, closed cup) Since 93% lactic acid is an aqueous solution, and it can be shown that even at elevated temperatures, its vapour consist mainly of water, and it will not flash at temperatures at least as high as 130 °C, it is stated that 93% lactic acid will not auto-ignite.			A3.12-02 A3.2-02	

Section A3 **Physical and Chemical Properties of Active Substance (LACTIC ACID 93% SOLUTION IN WATER)**

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
	EC A.15 DIN 51794 IEC 79-4	92.8% solution in water	400°C at atmospheric pressure (1011.4 – 1018.9 hPa)	At this temperature, water is flash-evaporated, leaving finely divided lactic acid; the flammability and autoflammability of such a material is akin to a dust conflagration.	Y		A3.11-01 Baltussen (2009)	
3.12 Flash-point (IIA3.9)		88% solution in water pure	> 150°C	Holten page 38: Flash Point No exact determination of the flash point has been performed; it is, however, not less than 74°C, determined in closed cup for an acid of not less than 88% by weight. From A3.12-02: A final simple experiment in which a small cup, filled with lactic acid (100%), was put in silicone oil of 150°C, it was proven that the flashpoint lies above 150°C. It was not possible to put the lactic acid on fire.	N		A3.12-01 Holten (1971a) A3.12-02	

Section A3 **Physical and Chemical Properties of Active Substance (LACTIC ACID 93% SOLUTION IN WATER)**

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.13 Surface tension (IIA3.10)		79% free acid	@ 25°C: 44.9 mN/m				A3.13-01 Van Dongen (2007e)	3.13
		[redacted]	[redacted]	[redacted]			[redacted]	3.13

Section A3 **Physical and Chemical Properties of Active Substance (LACTIC ACID 93% SOLUTION IN WATER)**

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
		[redacted]	[redacted]	[redacted]			[redacted]	3.13
		[redacted]	[redacted]				[redacted]	3.13

Section A3 Physical and Chemical Properties of Active Substance (LACTIC ACID 93% SOLUTION IN WATER)

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
		0.093% lactic acid in water (1 g/L active substance in water)	70.7 mN/m	Test was done according to OECD 115.			A3.13-05 Baltussen (2008)	3.13
3.14 Viscosity (-)		80% @ 25°C 88.6% @ 25°C	18.4 cP 36.9 cP				A3.14-01 Van Dongen (2007f)	
3.15 Explosive properties (IIA3.11)				From structural reasons and composition of the substance it can be concluded that the substance has no explosive properties.				
3.16 Oxidizing properties (IIA3.12)				From structural reasons and composition of the substance it can be concluded that the substance has no oxidizing properties.				
3.17 Reactivity towards container material (IIA3.13)			No reactivity was observed in the stability test.				A3.10-01 A3.10-2	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2009/03/01
3.1.1 Melting point	3.1.1.a The correct quotation of the following field entries is: Purity: pure, crystalline solid lactic acid Results: 53 °C, pressure: not specified Reference: C.H. Holten, Lactic acid, Verlag Chemie, Weinheim, 1971, S. 22. The given remark is not necessary to be mentioned
Conclusion	
Reliability	2
Acceptability	acceptable
Remarks	
Date	2009/03/01
3.1.1 Melting point	3.1.1.b Purity: 93 % L-(+)-Lactic acid Results: no melting until – 80 °C Remarks: Expert statement
Conclusion	
Reliability	4
Acceptability	acceptable
Remarks	
Date	2009/03/01
3.1.2 Boiling point	3.1.2.a Remarks/Justification: It`s not possible to give a single boiling point for 93 % L-(+)-Lactic acid. [redacted] Reference: Van Dongen (2006b)A3.1.2-01
Conclusion	Adopt applicant´s revised version
Reliability	4
Acceptability	acceptable
Remarks	

Date	2009/03/01
3.1.2 Boiling point	3.1.2.b [redacted] Purity: 100 % L-(+)-Lactic acid Results: 204.2 °C (calculated) Reference: Van Dongen (2006b) A3.1.2-01
Conclusion	Adopt applicant´s revised version
Reliability	2
Acceptability	acceptable
Remarks	

Date	2009/03/01
3.1.3 Bulk density/relative density	The correct quotation of the following field entries is: Purity: 93 % L-(+)-Lactic acid Results: 1.213 (T = 20 °C) (calculation from literature values) Densities of aqueous solutions of Lactic acid of various concentrations have been determined in literature. They vary almost linearily with concentration and temperature. The density of the 93 % L-(+)-Lactic acid is calculated using these results. The temperature was corrected to 20 °C according to the submitted values. Reference: C.H. Holten, Lactic acid, Verlag Chemie, Weinheim, 1971, S. 23-27.
Conclusion	Adopt applicant´s revised version
Reliability	2
Acceptability	acceptable
Remarks	

Date	2009/03/01
3.2 Vapour pressure	3.2.a The correct quotation of the following field entries is: Method: 92/69/EC, A.4 (Calculation, modified Grain Method) Purity: 100 % L-(+)-Lactic acid Results: 0.4 Pa (T = 20°C) Reference: G.P. v. Lieshout, EQUI2.BAS, May 1996
Conclusion	
Reliability	2
Acceptability	acceptable
Remarks	

Date	2009/03/01
3.2 Vapour pressure	3.2.b
	Due to the high water part, it is considered not to be scientific to determine or calculate the vapour pressure of a 93 % L-(+)-Lactic acid solution. The result of 670 Pa is only the partial vapour pressure of the water of the solution and it does not completely characterise the 93 % L-(+)-Lactic acid.
Conclusion	
Reliability	4
Acceptability	acceptable
Remarks	

Date	2009/03/01
3.2.1 Henry`s Law Constant	The Henry`s Law constant is not determinable for a 93 % aqueous solution of L-(+)-Lactic acid [redacted].
Conclusion	
Reliability	4
Acceptability	acceptable
Remarks	No further requirement.

Date	2009/03/01
3.3 Appearance	
3.3.1 Physical state	The correct quotation of the following field entries due to the safety data sheet is: Method: visual assessment Purity: 88 % L-(+)-Lactic acid Results: liquid (aqueous solution) GLP: N Reference: Safety data sheet of L-(+)-Lactic Acid Purac
Conclusion	Adopt applicant´s revised version
Reliability	2
Acceptability	acceptable
Remarks	Appearance of a 93 % solution is indistinguishable from the appearance of an 88 % solution.

Date	2008/07/07

3.3 Appearance	
3.3.2 Colour	The correct quotation of the following field entries due to the safety data sheet is: Method: visual assessment Purity: 88 % L-(+)-Lactic acid Results: colourless to yellow light brown, ≤ 100 Apha GLP: N Reference: Safety data sheet of L-(+)-Lactic Acid Purac
Conclusion	Adopt applicant´s revised version
Reliability	2
Acceptability	acceptable
Remarks	Appearance of a 93 % solution is indistinguishable from the appearance of an 88 % solution.
Date	2008/07/07
3.3 Appearance	The correct quotation of the following field entries due to the safety data sheet is:
3.3.3 Odour	Method: olfactory assessment Purity: 88 % L-(+)-Lactic acid Results: characteristic GLP: N Reference: Safety data sheet of L-(+)-Lactic Acid Purac
Conclusion	Adopt applicant´s revised version
Reliability	2
Acceptability	acceptable
Remarks	Appearance of a 93 % solution is indistinguishable from the appearance of an 88 % solution.
Date	2008/07/07

3.4 Absorption spectra	3.4.a UV
UV/VIS	The correct quotation of the following field entries according to the given spectrum and literature is:
	Method: UV/VIS-method (Water)
	Purity: 93 % L-(+)-Lactic acid, Batch: 0712001825
	Results: 210 nm (0.12 % w/w L-(+)-Lactic acid in water) [no absorption > 290nm]
	GLP: N
	Reference: R. Lieuwen, Labor journal 4, 6/2008.
	Reliability: 1
	3.4.b UV
	Method: UV/VIS-method
	Purity: Lactic acid, not stated
	Results: 210 nm [no absorption > 290nm]
	Reference: C.H. Holten, Lactic acid, Verlag Chemie, Weinheim, 1971, S. 87-88.
	Reliability: 2
Conclusion	Adopt applicant´s revised version
Reliability	1
Acceptability	acceptable
Remarks	

Date	2008/07/07
3.4 Absorption spectra	3.4 IR
IR	The correct quotation of the following field entries according to the given spectrum and literature is:
	Method: FT-IR (Golden Gate ATR)
	Purity: 91 % L-(+)-Lactic acid, Batch: 0704002390
	Results: ν = 3600 cm^{-1} (OH), 3000 (CH), 2900 (OH), 1800 (C=O).
	GLP: N
	Reference: P. Klabbers, Labor journal 10, 10/2007
	Reliability: 1
	3.4 IR
	Method: IR
	Purity: Lactic acid, not stated
	Results: ν = 3620 - 3605 cm^{-1} (OH), 2980 - 2950 (CH), 3050 (OH), 1755 - 1720 (C=O).
	Reference: C.H. Holten, Lactic acid, Verlag Chemie, Weinheim, 1971, S. 89.
	Reliability: 2
Conclusion	Adopt applicant´s revised version

Reliability	1
Acceptability	acceptable
Remarks	

Date	2008/07/07
3.4 Absorption spectra	3.4. NMR
NMR	The correct quotation of the following field entries according to the given literature is: Method: ^{1}H-NMR (60 MHz, D_2O, TMS) Purity: 90 % L-(+)-Lactic acid Results: δ = 1.4 ppm (CH_3, d), 4.5 (CH, q), 1.4 (CH_3, extra peak), 4.5 (CH, superimposed quartet), 5.3 (CH, quartet), about 5 (OH). [redacted] GLP: N Reference: C.H. Holten, Lactic acid, Verlag Chemie, Weinheim, 1971, S. 518/519. 3.4 NMR Method: ^{1}H-NMR (60 MHz, D_2O, TMS) Purity: not stated (crystalline, L-(+)-Lactic acid) Results: δ = 1.4 ppm (CH_3, d), 4.4 (CH, q), 5.1 (OH, COOH, s) GLP: N Reference: C.H. Holten, Lactic acid, Verlag Chemie, Weinheim, 1971, S. 516/517
Conclusion	Adopt applicant´s revised version
Reliability	2
Acceptability	acceptable
Remarks	

Date	2008/07/07
3.4 Absorption spectra **MS**	The MS spectrum for the pure compound in the expert statement is copied from the NIST Chemistry WebBook. Further spectra of the manufactured active substance are submitted, so this spectrum is not accepted. The correct quotation of the following field entries according to the given spectra is: Method: GC-MS/ 2 MS-spectra (70 eV) Purity: 93 % L-(+)-Lactic acid, Batch 0712001825 Results: m/z (lactic acid) = 45 (COOH+) m/z (Lactoyl lactic acid) = 89 (lactoyl), 74 ($C_2H_2O_3$), 45 (COOH+). Remarks: no mother ion is detected in both spectra GLP: N Reference: R. Lieuwen, Labor journal 4, 6/2008.

Conclusion	Adopt applicant´s revised version
Reliability	1
Acceptability	acceptable
Remarks	

Date	2008/07/07
3.5 Solubility in water	3.5.a The correct quotation of the following field entries is: Method: not stated Purity: not stated, crystalline L-(+)-Lactic acid Results: completely miscible with water Remarks/Justification: No GLP-study was submitted. The given result of 86.1 % monomeric lactic acid is not valid. [redacted] Reliability: 3 Reference: C.H. Holten, Lactic acid, Verlag Chemie, Weinheim, 1971, S. 53 3.5.b Remarks: The determination of the solubility in water of a 93 % active substance aqueous solution is not scientific. The test material is an aqueous solution itself. Furthermore no phase separation occurs during evaporation of water of lactic acid solutions of low concentration. Reference: Van Dongen (2007a) A 3.5-01
Conclusion	Adopt applicant´s revised version
Reliability	4
Acceptability	acceptable
Remarks	

Date	2008/07/07
3.6 Dissociation constant	The correct quotation of the following field entries is: Method: OECD 112 (conductometric method) Purity: not stated, crystalline L-(+)-Lactic acid Results: pKa = 3.86, T = 22.5 °C Reference: C.H. Holten, Lactic acid, Verlag Chemie, Weinheim, 1971, S. 62-67 GLP: N
Conclusion	Adopt applicant´s revised version
Reliability	2
Acceptability	acceptable

Remarks	The literature describes the conductometric method.
Date	2008/07/07
3.7 Solubility in organic solvents	The correct quotation of the following field entries is: [redacted]
Conclusion	Adopt applicant´s revised version
Reliability	2
Acceptability	acceptable
Remarks	
Date	2008/07/07
3.9 Partition coefficient n-octanol/water	3.9.a The correct quotation of the following field entries due to the submitted report is: Method: in house method (not described in detail in literature) Purity: crystalline L-Lactic acid Results: - 0.74 T = 20 °C GLP: N Reference: Gerorge P. van Lieshout 1997
Conclusion	Adopt applicant´s revised version
Reliability	2
Acceptability	acceptable
Remarks	
Date	2008/07/07

3.9 Partition coefficient n-octanol/water	3.9.b The determination of the partition coefficient n-octanol/water of a 93 % L-(+)-Lactic acid solution is not scientific, [redacted]
Conclusion	Adopt applicant´s revised version
Reliability	4 (not applicable)
Acceptability	acceptable
Remarks	

Date	2009/03/01
3.10 Thermal stability, identity of relevant breakdown products	3.10 a The correct quotation of the following field entries due to the submitted report is: Method: In-house method Purity/Specification: LOTNo. 0202000748, 80 % L-(+)-Lactic acid Results: thermally stable up to 5 years (25 °C, 60 % RH) Remarks: maximal deviation of 1 % (rel.) in 5 years, stability behaviour of the 93 % concentrated L-(+)-Lactic acid is assumed not to differ Reliability: 2 Reference: Van Dongen (2007) – Purac Internal Data 3.10 b The correct quotation of the following field entries due to the submitted report is: Method: In-house method Purity/Specification: LOTNo. 2010400029, 90 % L-(+)-Lactic acid Results: thermally stable up to 5 years (25 °C, 60 % RH) thermally stable up to 1 year (40 °C, 75 % RH) Remarks: maximal deviation of 1 % (rel.) in the given time Reliability: 2 Reference: Van Dongen (2007) –Purac Internal Report

Conclusion	Adopt applicant´s revised version
Reliability	2
Acceptability	acceptable
Remarks	

Date	2009/03/01
3.13 Surface tension	For the determination of the surface tension according to the EU method 92/69/EEC A.5 a solution with 1 g substance in 1 l water has to be used. Therefore only the study with this concentration of lactic acid (0.093 %) can be used to determine the surface activity: The correct quotation of the following field entries due to the submitted report is: Method: 92/69/EC A.5 Purity: 92.8 % L-(+)-Lactic acid (concentration: 1 g / l in water), Batch 0712002519 GLP: Y Reference: Baltussen (2008)
Conclusion	
Reliability	1
Acceptability	acceptable
Remarks	

Date	2008/07/07
3.14 Viscosity	The viscosity of the 93 % L-(+)-Lactic acid is not experimentally determined. No further study is requested, because it is only an additional data. The viscosities of the diluted concentrations do not cover the present concentration.
Conclusion	
Reliability	4
Acceptability	acceptable
Remarks	

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*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*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	