



Certificate of Analysis

1.00366.2500 (S)-Lactic acid about 90% EMPROVE® EXPERT Ph Eur,BP,E 270
Batch K55063366

	Spec. Values		Batch Values	
Assay (alkalimetric)	88.0 - 92.0	%	89.8	%
Assay (stereochemical purity of (S)-lactic acid)	≥ 95.0	%	98.5	%
Identity (IR-spectrum)	passes test		passes test	
Identity (pH)	passes test		passes test	
Identity (Density)	passes test		passes test	
Identity (Lactat)	passes test		passes test	
Identity (assay)	passes test		passes test	
Appearance	clear, oily liquid, not more intense in color than reference solution Y ₆		clear, oily liquid, not more intense in color than reference solution Y ₆	
Ether-insoluble substances	passes test		passes test	
Citric, oxalic and Phosphoric acids	passes test		passes test	
Density (d 20/20)	1.20 - 1.21		1.21	
Chloride (Cl)	≤ 0.2	%	≤ 0.2	%
Sulfate (SO ₄)	≤ 200	ppm	≤ 200	ppm
As (Arsenic)	≤ 3	ppm	≤ 3	ppm
Ca (Calcium)	≤ 200	ppm	≤ 200	ppm
Fe (Iron)	≤ 10	ppm	≤ 10	ppm
Hg (Mercury)	≤ 1	ppm	≤ 1	ppm
Pb (Lead)	≤ 2	ppm	≤ 2	ppm
Ethanol	≤ 5000	ppm	≤ 5000	ppm
Acetic acid	≤ 5000	ppm	≤ 5000	ppm
Methanol	≤ 50	ppm	≤ 50	ppm
Other residual solvents (ICH Q3C)	excluded by manufacturing process		excluded by manufacturing process	
Sugars and other reducing substances	passes test		passes test	
Sulfated ash (600 °C)	≤ 0.10	%	≤ 0.10	%
Total aerobic microbial count (TAMC)	≤ 10 ²	CFU/ml	≤ 10 ²	CFU/ml
Total combined yeasts/moulds count (TYMC)	≤ 10 ²	CFU/ml	≤ 10 ²	CFU/ml
Bacterial endotoxins	≤ 5	I.U./g	< 1	I.U./g

Elemental impurity specifications have been set considering ICH Q3D (Guideline for Elemental Impurities). Class 1-3 elements are not likely to be present above the ICH Q3D option 1 limit, unless specified and indicated (*).

Corresponds to Ph Eur,BP, E 270

Conforms to the purity criteria on food additives according to European Commission directive 2008/84/EC.

Date of manufacture (DD.MM.YYYY) 22.12.2022

Date of examination (DD.MM.YYYY) 21.02.2023

Minimum shelf life (DD.MM.YYYY) 31.12.2027

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Dr. Sebastian Lips

Responsible laboratory manager quality control

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