

Certificate of Analysis

1.06445.0000 Sodium L-glutamate monohydrate EMPROVE® EXPERT ChP,FCC,NF,

E 621

Batch K56525445

	Spec. Values		Batch Values	
Assay (perchloric acid titration, calculated on dried substance)	99.0 - 100.5	%	100.1	%
Identity (IR-spectrum)	passes test		passes test	
Identity (wet chemistry)	passes test		passes test	
Identity (TLC)	passes test		passes test	
Appearance	white to almost white, crystalline powder or fine crystals		passes test	
Appearance of solution (100 g/l, water)	colorless and not more intense in turbidity than control solution according to NF and FCC		passes test	
Transmittance of solution (100 g/l, water)	≥ 98.0	%	99.4	%
Spec. rotation (α 20/D, 100 g/l, hydrochloric acid 2 mol/l, calc. on dried substance)	+24.8 to +25.3	0	+25.3	0
oH (50 g/l CO₂-free water)	6.7 - 7.2		7.0	
Alkalinity or acidity (100 g/l, water)	6.7 - 7.2		7.0	
Chloride (CI)	≤ 500	ppm	≤ 500	ppm
Sulfate (SO ₄)	≤ 300	ppm	≤ 300	ppm
NH₄ (Ammonium)	≤ 200	ppm	≤ 200	ppm
Fe (Iron)	≤ 10	ppm	≤ 10	ppm
Heavy metals (as Pb)	≤ 10	ppm	≤ 10	ppm
Al (Aluminium)	≤ 5	ppm	≤ 5	ppm
As (Arsenic)	≤ 1	ppm	≤ 1	ppm
Mn (Manganese)	≤ 15	ppm	≤ 15	ppm
Pb (Lead)	≤ 1	ppm	≤ 1	ppm
Cu (Copper)	≤ 10	ppm	≤ 10	ppm
Zn (Zinc)	≤ 10	ppm	≤ 10	ppm
Other amino acids (TLC)	≤ 0.5	%	≤ 0.5	%
5-Oxopyrrolidine-2-carboxylic acid (Pyroglutamic acid)	≤ 0.2	%	< 0.1	%
Residual solvents (ICH Q3C)	excluded by manufacturing process		excluded by manufacturing process	
Loss on drying (100 °C, 5 h)	≤ 0.1	%	0.1	%
Bacterial endotoxins	≤ 25	I.U./g	≤ 25	I.U./g
Total aerobic microbial count (TAMC)	≤ 500	CFU/g	≤ 500	CFU/g
Total combined yeasts/moulds count (TYMC)	≤ 100	CFU/g	≤ 100	CFU/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 (*).

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Corresponds to ChP, NF, FCC, E 621

Conforms to the purity criteria on food additives according to the current European Commission Regulation.

Date of manufacture (DD.MM.YYYY) 27.11.2024 Date of examination (DD.MM.YYYY) 21.03.2025 Minimum shelf life (DD.MM.YYYY) 30.11.2027

Dr. Michael Memmel

Responsible laboratory manager quality control

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