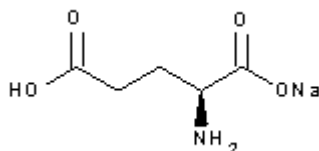


PRODUCT CODE: Z41683**Sodium L-Glutamate 1-hydrate (USP-NF) low endotoxin pure, pharma grade**C₅H₈NNaO₄·H₂ONaCOOHCOONH₂CH(CH₂)₂·H₂O

M.= 187,13

CAS [6106-04-3]

EINECS 205-538-1

TARIC 2922 42 00 10

SYNONYMS: (S)-(+)-2-Aminoglutaric Acid mono-Sodium Salt, (S)-Glutamic Acid mono-Sodium Salt**PHYSICAL DATA:** crystalline powder, White, Soluble in water. M.P.: 225 - 240 °C • pH(10% sol.) 6,5 - 7,5 •**BIBLIOGRAPHY:** Merck Index **12**, 6.337 13, 6.278 Römp **8**, **2736** • Beilstein **4**, **488 IV**, **3031** • BRN 4164348 • USP - **NF 37** • F.C.C **11 12** • BOE **243(8-10-2009)** • Regulation (EU) n° 231/2012 •**HAZARDOUS:** RTECS: MA 1578000 • LD50 oral mus 16.400 mg/kg • LD50 oral rat 16.600 mg/kg •**SPECIFICATIONS:**

Assay (Perchl. Ac.)	99,0-100,5%
Identity :	
Identity according to Pharmacopoeias:	passes test
pH of 5% solution	6,7-7,2
Specific rotation [α] ₂₀ /D _{c=10} (in HCl 2 mol/l)	+24,8 - +25,3°

Maximum limit of impurities

Insoluble matter in H ₂ O	0,05 %
Loss on drying at 100°C	0,5%
Chloride (Cl)	0,2%

Sulfate (SO ₄)	0,05%
Clarity and colour of solution	passes test
Residual solvents (USP)	passes test
Maximum microbial limits:	
Bacterial endotoxins	0,05 IU/mg
Total Aerobic Microbial Count (TAMC)	100 cfu/g
Pb	0,001 %
Elemental impurities (ICH Q3D):	
Class 1	
Cd	0,5 ppm
Pb	10 ppm
As	1,5 ppm
Hg	1,5 ppm
Class 2A	
Co	5 ppm
V	10 ppm
Ni	20 ppm
Class 2B	
Tl	10 ppm
Au	10 ppm
Pd	10 ppm
Ir	10 ppm
Os	10 ppm
Rh	10 ppm
Ru	10 ppm
Se	15 ppm
Ag	15 ppm
Pt	10 ppm
Class 3	
Li	55 ppm
Sb	120 ppm
Ba	140 ppm
Mo	25 ppm
Cu	250 ppm
Sn	600 ppm
Cr	25 ppm