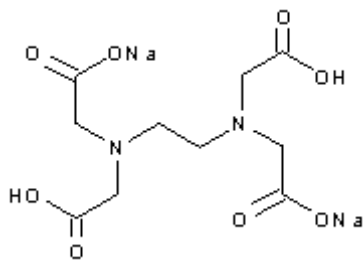
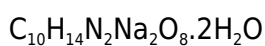


**PRODUCT CODE: 631669****EDTA Disodium Salt 2-hydrate (Ph. Eur, BP, USP) GMP - IPEC grade**

M. = 372,24

CAS [6381-92-6]

EINECS 205-358-3

TARIC 2922 49 85 90

SYNONYMS: Disodium Edetate, Disodium EDTA, Ethylenedinitriletetraacetic Acid Disodium salt, N,N'-1,2-Ethanediy-bis[N-(Carboxymethyl)Glycine]

PHYSICAL DATA: crystalline powder, White, Soluble in water 100 g/l M.P.: 248 - 254 °C • pH(50 g/l) 4 - 5 • Ign. T.: >200 °C •

BIBLIOGRAPHY: Merck Index **12**, 3.556 13, 633 Safety **2**, **1606 D** • Beilstein **4**, **III**, **1187 IV**, **2451** • BRN 3900609 • Fieser **1373** • ACS **XI** • ISO 6353/2-1983 R - 12, 6 • BP.**2018** • USP **41** • Ph. Eur. **8.0** (2014) **9.0** (2017) • F.C.C **10 11** •

HAZARDOUS: RTECS: AH 4375000 • LD50 oral rat 2.800 mg/kg • LC50 rat 30mg/m3 / (5 d, 6h) • TWA (If inhaled) 10 mg/m3 TWA (respirable dust) 3 mg/m3 DNEL 2,5 mg/m3 DNEL 1,5 mg/m3 DNEL 25mg/kg/24h PNEC 2.5mg/l PNEC 0.25mg/l PNEC 1.4mg/l PNEC 50mg/l PNEC 0.84mg/kg



H: H332 • H373 •

P: P260 • P261 • P271 • P304+P340 • P312 • P314 • P501 •

OBSERVATIONS: Storage away from direct light. •

SPECIFICATIONS:

Assay (Compl.)	98,5 - 101,0 %
Assay (Compl.) (calc. a.a.s)	99,0 - 101,0 %
Identity :	
Identity according to Pharmacopoeias:	
Identity A	IR passes test
Identity Sodium	passes test
Identity Complexone	passes test
pH sol. 5 %	4,0 - 5,5

Maximum limit of impurities

Appearance of solution	
Appearance Clear < formazin I	passes test
Appearance Colourless	passes test
Loss on drying at 150°C	8,7 - 11,4 %
Residual solvents (Ph.Eur/USP)	passes test
Nitrilotriacetic acid [CH ₂ COOH) ₃ N]	0,1 %
Heavy metals (as Pb)	0,0020 %

Fe	0,0080 %
Ca	passes test

Elemental impurities (ICH Q3D):

Class 1	
Cd	0,5 ppm
Pb	0,5 ppm
As	1,5 ppm
Hg	2 ppm

Class 2A	
Co	5 ppm
V	10 ppm
Ni	20 ppm

Class 2B	
Tl	0,8 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

Ed.: 4 . Vig.: 18.07.2017 .

Prod.: 631669