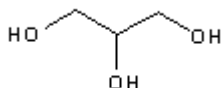


**PRODUCT CODE: 631339****Glycerol (Ph. Eur, BP, USP) GMP - IPEC grade**

M.= 92,10

CAS [56-81-5]

EINECS 200-289-5

TARIC 2905 45 00 00

SYNONYMS: 1,2,3-Propanetriol, Glycerol

PHYSICAL DATA: liquid, Clear, viscous, Colourless, Miscible with water • Hygroscopic • D 20/4 1,262 • M.P.: 17,8 °C • B.P.: 290 °C • pH(100g/l) 5 • n_{20/D} : 1,474 • Flash P.: 176 °C • Ign. T.: 429 °C • Vap. press. (20 °C) 0,01 hPa • Viscosity 20 °C 1.400 mPa.s • Dielec. constant 20 °C 42,5 • Heat evap. 290 °C 826 KJ/Kg •

BIBLIOGRAPHY: Merck Index **12**, 4.493 13, 4.497 Sax **GGA000** • Safety **2**, **1782 D** • Römpp **8**, **1512** • Kühn-Birett **G 4** • Ullmann (**5.**) **12**, 477 • Beilstein **1**, **502 I**, **266 II**, **575 III**, **2297 IV**, **2751** • BRN 635685 • ACS **XI** • ISO 6353/3-1987R - 64, 30 • BP. **2018** • USP **41** • Ph. Eur. **8.0** (2014) **9.0** (2017) • F.C.C **10 11** • BOE **243** (8-10-2009) • Regulation (EU) n° 231/2012 BS 2621-5 •

HAZARDOUS: RTECS: MA 8050000 • LD50 oral rat 12.600 mg/kg • VLA-ED 10 mg/m³

WEIGHT/VOLUME INFORMATION: 1l~1,259 kg 1kg~0,794 l

SPECIFICATIONS:

Assay (calc. a.a.s)

99,0-101,0%

Identity :

Identity according to Pharmacopoeias:

Identity (A Ph. Eur / USP)

passes test

Identity (B Ph. Eur / USP)	passes test
Identity (C Ph. Eur / USP)	passes test
Identity (D Ph. Eur)	passes test
Density at 25/25	$\geq 1,249$
Refractive Index $n_{20/D}$	1,470-1,475
Specific gravity at 25°C	$\geq 1,249$

Maximum limit of impurities

Appearance of solution	
Appearance Transparent < formazin 50	passes test
Appearance Colourless	passes test
Acidity or alkalinity	< 0.2 ml NaOH 0.1M
Residue on ignition (as SO ₄)	0,01 %
Sugars	passes test
Chloride (Cl)	0,0010%
Sulfate (SO ₄)	0,002%
Color	passes test
Halogenated compounds Ph. Eur (as Cl)	0,0035%
Chlorinated compounds USP (Cl)	0,003%
Residual solvents (Ph.Eur/USP)	passes test
Aldehydes (as CH ₂ O)	0,0010%
Esters Ph. Eur.	passes test
Fatty Acids and Esters (USP)	< 1 ml NaOH 0.1M
Impurity A and related substances (C.G.)	
Impurity A (Diethyleneglycol)	0,1%
Individual Tr < Tr glycerine	0,1%
Total impurities Tr > Tr glycerine	0,5%
Diethyleneglycol and ethyleneglycol impurities (CG)	
Diethyleneglycol	0,1%
Ethyleneglycol	0,1%
Water (H ₂ O)	2,0 %
Heavy metals (as Pb)	0,0005%

Elemental impurities (ICH Q3D):

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

DOES NOT COME FROM ANIMAL ORIGIN.

Ed.: 4 . Vig.: 20.09.2017 .

Prod.: 631339