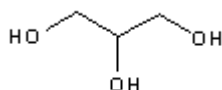


**PRODUCT CODE: 141339****Glycerol (USP, BP, Ph. Eur.) pure, pharma grade**C<sub>3</sub>H<sub>8</sub>O<sub>3</sub>

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<sub>20</sub>/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. constant20 °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** • Römp **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.2020** • **USP 42** • Ph. Eur. **9.0** (2017) **10.0** (2020) • 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/m<sup>3</sup>

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

**SPECIFICATIONS:**

|  |               |
|--|---------------|
| Assay (C <sub>3</sub> H <sub>8</sub> O <sub>3</sub> ) calc. a.d.s. | 99,0-101,0%   |
| Identity :   |               |
| Identity according to Pharmacopoeias:                              | passes test   |
| Density at 25/25   | >= 1,249      |
| Density at 20/20   | 1,258 - 1,268 |

Refractive Index n<sub>20</sub>/D 1,470-1,475

**Maximum limit of impurities**

|  |             |
|--|-------------|
| Appearance of solution                       | passes test |
| Acidity or alkalinity                        | passes test |
| Residue on ignition (as SO <sub>4</sub> )    | 0,01 %      |
| Sugars                                       | passes test |
| Chloride (Cl)                                | 0,001%      |
| Ammonium (NH <sub>4</sub> )                  | 0,001%      |
| Sulfate (SO <sub>4</sub> )                   | 0,002%      |
| Color  | passes test |
| Halogenated compounds (as Cl)                | 0,003 %     |
| Residual solvents (Ph.Eur/USP)               | passes test |
| Organic impurities - Related substances      |             |
| Individual                                   | 0,1 %       |
| Total  | 1,0 %       |
| Aldehydes (as CH <sub>2</sub> O)             | 0,0010%     |
| Diethyleneglycol (USP)                       | 0,025%      |
| Ethylenglycol (USP)                          | 0,025%      |
| Esters                                       | passes test |
| Impurity A and related substances (Ph. Eur.) |             |
| Impurity A (Diethyleneglycol)                | 0,1 %       |
| Individual Tr < Tr glycerine                 | 0,1 %       |
| Total impurities Tr > Tr glycerine           | 0,5 %       |
| Water (H <sub>2</sub> O)                     | 0,5 %       |

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  |

## **GLYCERINE OF VEGETABLE ORIGIN**

Ed.: 12 . Vig.: 09.05.2019 .

Prod.: 141339