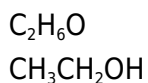


**PRODUCT CODE: 631085****Ethanol 96% v/v (Ph.Eur, BP, USP) GMP - IPEC grade**

M.= 46,07

CAS [64-17-5]

EINECS 200-578-6

TARIC 2207 10 00 90

SYNONYMS: Ethyl Alcohol

PHYSICAL DATA: liquid, Clear, Colourless, Miscible with water and most of the solvents • D 20/4 0,805 • M.P.: -114,1 °C • B.P.: 78,5 °C • n_{20/D} : 1,361 • Flash P.:14 °C • Ign. T.:~425 °C • Vap. press. (20 °C) 57,26 hPa • Viscosity 1,2 mPa.s • Expl. limit 2,5 %(V) 13,5 %(V) •

BIBLIOGRAPHY: Merck Index **12**, 3.806 13, 3.795 Sax **EFU300** • Ullmann (**5.**)9 , 587 • Beilstein **1** , **IV** , **1289** • BRN 1718733 • ACS **XI** • BP.**2018** • USP **41** • Ph. Eur. **8.0** (2014) **9.0** (2017) • F.C.C **10 11** • Directive 88/344/E.C.E.92/115/E.C.E.94/52/EC97/60/EC (27/10/1997) 2009/32/CE • DAB 10, Royal Decree 472/1990 (6/4/1990) , 2667/1998 (11 /12/1998), 1101/2011 (22/7/2011), F. U. IX , 74, Ph.F. X , 15 •

HAZARDOUS: C.E: 603-002-00-5 • RTECS: KQ 6300000 • LD50 oral rat 6.200 - 15.000 mg/kg / (OECD 401) • LC50 rat >50mg/m³ / (OECD 403) • VLA-ED 1.000 ppm 1.920 mg/m³



H: H225 • H319 •

P: P210 • P233 • P240 • P241 • P242 • P501 • P243 • P280 • P303+P361+P353 • P370+P378 • P403+P235 • P264 • P305+P351+P338 • P337+P313 • P264 • P305+P351+P338 • P337+P313 •

TRANSPORT REGULATIONS: UN: 1170 • ADR: 3/II • IMDG: 3/II • IATA: 3/II • PAX: 353 • CAO: 364 • (D/E) •

WEIGHT/VOLUME INFORMATION: 1l~0,805 kg 1kg~1,242 l

OBSERVATIONS: May be subject to special tax. • Storage away from direct light, away from sources of ignition and

heat. Storage at temperature below 25°C. •

SPECIFICATIONS:

Assay (v/v) (d at 20°C)	95,1-96,9 %
Assay (v/v) (d at 15.56/15.56°C)	94,9-96,0%
Assay (w/w) (d at 20°C)	92,6-95,2%
Assay (w/w) (d at 15.56/15.56°C)	92,3-93,8%
Identity :	
Identity according to Pharmacopoeias:	
Identity (A Ph. Eur / USP)	passes test
Identity (B Ph. Eur / USP)	IR passes test
Identity (C Ph. Eur)	passes test
Identity (D Ph. Eur)	passes test
Density at 20/20	0,805-0,812
Specific gravity at 15.56° C	0,812-0,816

Maximum limit of impurities

ABS	
at λ 240 nm	0,40
at λ 250-260 nm	0,30
at λ 270-340	0,10
Absorption curve, smooth at λ	passes test
Appearance	passes test
Appearance Clarity of solution USP	passes test
Appearance Colour of solution USP	passes test
Acidity or alkalinity (in CH ₃ COOH)	0,0030%
Non-volatile matter (w/v)	0,0025 %
Residual solvents (Ph.Eur/USP)	passes test
Volatile impurities (G.C.)	
Methanol	0,0200%
Acetaldehyde and acetal	0,0010%
Benzene	0,0002%
Total other impurities	0,0300%

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