



PRODUCT CODE: 146075

Polysorbate 80 (USP-NF, BP, Ph. Eur.) pure, pharma grade

CAS [9005-65-6] EINECS 500-019-9
TARIC 3402 13 00 90

SYNONYMS: Polyoxyethylene 20 Sorbitane mono-Oleate

PHYSICAL DATA: liquid, Clear, Yellow to brownish, Soluble in water. D 20/4 1,08 • B.P.:> 100 °C • pH(50 g/l)5
- 7 • n₂₀/D : 1,472 • Ign. T.:>180 °C •

BIBLIOGRAPHY: Merck Index **13**, 7.664 Sax **PKG250** • **BP.2018** • **USP -NF 36** • Ph. Eur. **8.0** (2014) 5.4 , 4007
9.0 (2017) 5.4 , 4007 6.3 , 6.5 , 6.6 • F.C.C **IV308** • **BOE 243**(8-10-2009) • Regulation (EU) n° 231/2012 •

HAZARDOUS: RTECS: WG 2932500 • LD50 oral mus 25.000 mg/kg • LD50 oral rat 55.000 mg/kg • LD50 ipr mus
7.600 mg/kg LD50 ipr rat 6.804 mg/kg

WEIGHT/VOLUME INFORMATION: 1l~1,075 kg 1kg~0,93 l

OBSERVATIONS: Storage away from direct light. •

SPECIFICATIONS:

Identity :	
Identity according to Pharmacopoeias:	passes test
Density at 25/25	1,06-1,09
Viscosity at 25°C	300-500 cSt

Maximum limit of impurities

Residue on ignition (as SO ₄)	0,2 %
Acidity value	2,0

Hydroxyl value	65-80
Iodine value	18-24
Peroxide value	10,0
Saponification value	45-55
Total ashes	0,25%
Residual solvents (Ph.Eur/USP)	passes test
Composition of fatty acids:	
Myristic acid	5,0 %
Palmitic acid	16,0 %
Palmitoleic acid	8,0 %
Stearic acid	6,0 %
Oleic acid	58,0 - 85,0 %
Linoleic acid	18,0 %
Linolenic acid	4,0 %
Ethylene Oxide	0,0001%
Dioxan	0,001%
Reducing impurities	passes test
Water (H2O)	3,0 %
Heavy metals (as Pb)	0,001%

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	5 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