



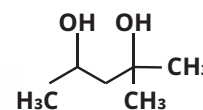
Technical Data Sheet

Hexylene glycol

USP-NF

Applications

Hexylene glycol is widely used in the pharmaceutical industry for topical dosage forms as a solvent, Co-solvent and permeation enhancer.



General Information

Pharmacopeia Status	: USP-NF
CAS No	: 107-41-5
EC No.	: 203-489-0
Appearance/Description	: Clear colourless viscous liquid. Absorbs moisture when exposed to moist air.
Molecular Formula	: C ₆ H ₁₄ O ₂
Molecular Mass	: 118.17 g/mol

Marketed Formulation

- Diclofenac gel
- Clobetasol propionate ointment & many more...

Quality and Regulatory Support

- GMP and ISO certification
- EXCiPACT certification
- Nitrosamine impurity risk assessment
- Elemental impurity risk assessment
- Residual solvent declaration
- Genotoxic impurity declaration
- Vendor questionnaire and site audit
- CMC documentation
- Regulatory queries

Key Product Attributes

- Manufacturing and packing under GMP environment
- Control of sub-visible particles

Pack Mode

- 1 kg, 2.5 Litre glass bottle
- 25 Litre HDPE drum

Stability and Storage Conditions

Keep container tightly closed in a cool & well-ventilated area.

Safety and Handling Information

Keep away from heat and sources of ignition. Evaporate the residue under a fume hood as empty containers pose a fire risk. Ground all equipment containing material. Do not ingest or breathe gas/fumes/ vapor/spray. Wear suitable protective clothing. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes. Keep away from incompatibles such as oxidizing agents, acids.

Pharmaceutical Specifications

Description	Clear colourless viscous liquid. Absorbs moisture when exposed to moist air
Solubility	Miscible with water and with many organic solvents, including alcohol, ether, chloroform, acetone, and hexanes
Identification A (By IR)	IR spectra of the sample should be concomitant with IR spectra of the corresponding standard
Identification B (By GC)	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution
Assay (By GC)	98.0% - 102% (On anhydrous basis)
Organic impurities : Acetone	NMT 0.1%
Organic impurities : 2-Propanol	NMT 0.1%
Organic impurities : 4-Methylpentan-2-one	NMT 0.1%
Organic impurities: 4-Methylpentan-2-ol	NMT 0.1%
Organic impurities: Diacetone alcohol	NMT 0.1%
Organic impurities; Any other individual impurity	NMT 0.1%
Organic impurities; Total impurities	NMT 1.0%
Specific gravity	0.917 - 0.923
Refractive index	1.424 - 1.430
Acidity	NMT 0.20 ml of 0.10 N sodium hydroxide should require
Water	NMT 0.5%

Shipping Information

By Sea, Air and Road

Nature: Non Hazardous

See the Material Safety Data Sheet on www.finarchemicals.com

Note : The information contained herein is to our best knowledge true and accurate, but all recommendations or suggestions are made without guarantees since the conditions of use are beyond our control. Finar disclaims any liability incurred with the use of this data or suggestions.

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