



IOI OLEOCHEMICAL

PHARMA

MIGLYOL[®] 812 N EXCIPIENT

TECHNICAL DATA SHEET

**Ph. Eur. / B.P. (current version):
USP (current version):**

**Triglycerides, Medium-Chain
Medium-Chain Triglycerides**

DESCRIPTION

MIGLYOL® 812 N is a triglyceride ester of saturated caprylic and capric fatty acids and glycerol. Fatty acids and glycerol are derived from vegetable sources.

MIGLYOL® 812 N is a clear, virtually colourless liquid of neutral odour and taste. It is a very good solvent for drugs.

APPLICATION

Parenteral Products

Tablets, dragees:	Anti-sticking, polishing agents.
Soft gelatine capsules:	Chemically neutral, low-viscosity carrier oil, absorption promoter.
Drops:	Carrier, solvent, and absorption promoter.
Suspensions, syrups:	Carrier and absorption promoter for antibiotics etc.
Aerosol products:	Carrier and solvent (glycerol trinitrate etc.).

Dietetic products & Nutraceuticals

Medium chain triglycerides (MCT) differ from natural fats (LCT).
With regard to these essential properties:
quick metabolism, not stored as body fat.
Physiological caloric value = 8,2 kcal/g (34,3 kJ/g)
compared with LCT = 9,2 kcal/g (38,5 kJ/g).
Different absorption and metabolism properties:
MCT is partially utilized if fat resorption disorders exist.

Topical therapeutics

Psoriasis Treatment and Antipruritics: Readily absorbent, scale-detaching and keratin softening oil component, particularly in combination with Vitamin A.

Ointments:

Non-oxidizing, absorption-promoting, non-occlusive oil component with excellent spreadability.

Rectal products

Anti-nucleating and dispersing aid for active ingredients in Hard Fat (WITEPSOL®) suppositories.



CHEMICAL AND PHYSICAL PROPERTIES

Tests	Values	Typical values	Units	Methods
Acid value	max. 0.2	0.02	mg KOH/g	Ph. Eur. 2.5.1
Hydroxyl value	max. 10	3	mg KOH/g	Ph. Eur. 2.5.3
Water	max. 0.2	0.02	%	Ph.Eur. 2.5.32
Viscosity at 20 °C	25 – 33	30	mPa·s	Ph. Eur. 2.2.9
Colour	max. 60	24	APHA	ISO 6271
Caprylic acid (C _{8:0})	50.0 – 80.0	58	%	Ph. Eur. 2.4.22
Capric acid (C _{10:0})	20.0 – 50.0	41	%	Ph. Eur. 2.4.22

Above mentioned tests are a selection of relevant parameters and do not represent the complete current sales specification.

MIGLYOL® 812 N fully complies with the requirements of the current Ph. Eur. monograph "Triglycerides, Medium-Chain".

MIGLYOL® 812 N is **very pure because of its carefully selected raw materials**. As a result of tightly controlled manufacturing process microorganisms are practically absent because of very low levels of water, i.e. microbes cannot sustain.

MIGLYOL® 812 N is free from additives such as antioxidants, solvents and catalyst residues.

MIGLYOL® 812 N has the following advantages compared to edible oils:

- low in impurities (as a result of production according to EU GMP guidelines)
- high stability against oxidation
- liquid at 0°C

At low temperatures parts of the triglycerides may crystallize. This phenomenon is completely reversible and has no impact on the product's quality.

Solubility

MIGLYOL® 812 N is soluble at 20°C in the following solvents:

Hexane, toluene, diethyl ether, ethyl acetate, acetone, isopropanol and ethanol 96%.

MIGLYOL® 812 N is miscible in all ratios with natural oils.

MIGLYOL® 812 N is not soluble in water and glycerol.



ADDITIONAL INFORMATION

Regulatory Information

The fatty acids used for the production of MIGLYOL® 812 N comply with CFR 21, § 172.860 and is classified as GRAS. It has been assigned the type IV DMF no. 800.

Toxicological data

The LD₅₀ value on the rat is > 2 g/kg body weight.

Oral Tolerance

Acute oral toxicity (LD₅₀): more than 5 g/kg body weight.

Parenteral Tolerance

Intramuscular toxicity: no histopathological results.

Acute inhalation toxicity: no histopathological results.

Environmental tolerance

MIGLYOL® 812 N is readily biodegradable. Therefore it exhibits the same behaviour as natural fat products with a triglyceride structure.

Stability information

Stability testings according to ICH guidelines have been performed, showing very good stability results in longterm studies and accelerated studies which support the 36 months retest date. Specific information upon request.



PACKAGING UNITS

25 kg HDPE jerry cans, 180 kg steel drum with an inner laquer lining. 950 kg International Bulk Container (IBC).

The following packaging materials are recommended:

- High Density Polyethylene = HDPE
- Polytetrafluorethylene (PTFE)
- Polypropylene (PP)
- Metal (stainless steel)
- Glass

Material compatibility instructions and additional information

MIGLYOL® 812 N is a good solvent, like other low-viscosity hydrophilic ester oils. Some plastics, especially those containing plasticizers, tend to turn brittle or to expand.

Polystyrene and Polyvinylchloride (PVC) are no suitable packaging materials. Be careful when selecting resistant seal closure material (e.g. VITON® is recommended) and be careful of sufficient pull power because MIGLYOL® 812 N shows a high tendency to migrate.

HANDLING AND SHELF LIFE

If stored longterm in original tightly closed containers, dry, protected from light and moisture and below 25°C, the shelf life then is at least three years.

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