



IOI OLEOCHEMICAL

IOI Oleo GmbH
PHARMA

Technical Data Sheet | MIGLYOL® 812 N (Excipient)

Ph. Eur. / B.P. name: Triglycerides, Medium-Chain

USP name: Medium-Chain Triglycerides

1. Description

MIGLYOL 812 N is a triglyceride ester of saturated coconut/palmkernel oil derived caprylic and capric fatty acids and plant derived glycerol.

2. 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. 100	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

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



IOI OLEOCHEMICAL

**IOI Oleo GmbH
PHARMA**

Technical Data Sheet | MIGLYOL® 812 N (Excipient)

Ph. Eur. / B.P. name: Triglycerides, Medium-Chain

USP name: Medium-Chain Triglycerides

3. Properties

MIGLYOL 812 N is a clear, virtually colourless liquid of neutral odour and taste.

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. microbials cannot sustain. It is free of 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.

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.

4. Applications

Oral 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.).



IOI OLEOCHEMICAL

**IOI Oleo GmbH
PHARMA**

Technical Data Sheet | MIGLYOL® 812 N (Excipient)

Ph. Eur. / B.P. name: Triglycerides, Medium-Chain

USP name: Medium-Chain Triglycerides

**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.

5. Additional Information

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



IOI OLEOCHEMICAL

**IOI Oleo GmbH
PHARMA**

Technical Data Sheet | MIGLYOL® 812 N (Excipient)

Ph. Eur. / B.P. name: Triglycerides, Medium-Chain

USP name: Medium-Chain Triglycerides

6. Additional Information

6.1. Toxicological data

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

6.2. Oral Tolerance

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

6.3. Environmental tolerance

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

6.4. Stability information

Stability testings according to ICH guidelines have been performed, showing very good stability results in longterm studies and at elevated temperatures (6 months accelerated studies available). Specific information upon request.



IOI OLEOCHEMICAL

IOI Oleo GmbH
PHARMA

Technical Data Sheet | MIGLYOL® 812 N (Excipient)

Ph. Eur. / B.P. name: Triglycerides, Medium-Chain

USP name: Medium-Chain Triglycerides

7. Packaging Information

7.1. Material compatibility instructions

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 PVC are not 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 has a high tendency to migrate.

The following packaging materials are recommended:

- Low pressure polyethylene (High Density PE = HDPE)
- PTFE (PolyTetraFluorEthylene)
- PolyPropylene
- Metal (stainless steel)
- Glass

7.2. Packaging Units

IBC HDPE containers of 950 kg net, HDPE containers of 25 kg net, steel drums with an inner FDA approved lacquer lining of 190 kg net.

8. Storage and Shelf Life

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

All general and technical information is believed to be correct and is presented in good faith and based on IOI Oleo GmbH's present technical knowledge and that of all group companies. IOI Oleo GmbH makes no representations as to the completeness or accuracy thereof. Information is supplied upon the condition that the persons receiving same will make their own determination as to its suitability for their purposes prior to use. As far as legally possible, IOI Oleo GmbH will not be responsible for damages of any nature whatsoever resulting from the use of or reliance upon information. IOI Oleo GmbH reserves the right, in its sole discretion, to make any changes according to technological progress or further developments.

In particular, IOI Oleo GmbH makes NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, THAT THE PRODUCTS TO WHICH THE INFORMATION REFERS MAY BE USED WITHOUT INFRINGING THE INTELLECTUAL PROPERTY RIGHTS OF OTHERS, OR OF ANY OTHER NATURE HEREUNDER WITH RESPECT TO INFORMATION OR THE PRODUCT TO WHICH INFORMATION REFERS. IN NO CASE SHALL THE INFORMATION BE CONSIDERED A PART OF OUR TERMS AND CONDITIONS OF SALE.