IOI OLEOCHEMICAL

PHARMA

LIPID SOLUTIONS FOR INJECTABLES

IOI Oleo GmbH

OUR EXCIPIENTS FOR INJECTABLE FORMULATIONS

For injectable formulations, the selection of a pure excipient is key to ensure constant drug product quality, stability, efficacy, and finally patient safety.

IOI Oleo offers formulators a dedicated range of excipient-grade carrier oils with proven functionality and a trusted reputation with health authorities.

The MIGLYOL® range is regularly and successfully used for the development of IV, SC and IM injections; it meets the applicable quality standards and complies with various current regulations.

PRODUCT	CHEMICAL DESCRIPTION	LISTED IN	APPEARANCE	VISCOSITY mPa· s 20 ° C
MIGLYOL® 810 N	Triglyceride, Medium-Chain, MCT (ratio C8:C10 ~ 70:30%)	Ph. Eur., USP-NF, JPE, US DMF Type IV, No. 800	Almost colorless and odorless oily liquid	~ 28.0
MIGLYOL® 812 N Excipient	Triglycerides, Medium-Chain, MCT neutral oil (ratio C8:C10 ~ 60:40%)	Ph. Eur., USP-NF, JPE, US DMF Type IV, No. 800	Almost colorless and odorless oily liquid	~ 30.0
MIGLYOL® 840	Propylene Glycol Dicaprylocaprate	Ph. Eur., USP–NF	Almost colorless and odorless oily liquid	~ 11.0

CHARACTERISTICS AND TYPICAL PROPERTIES

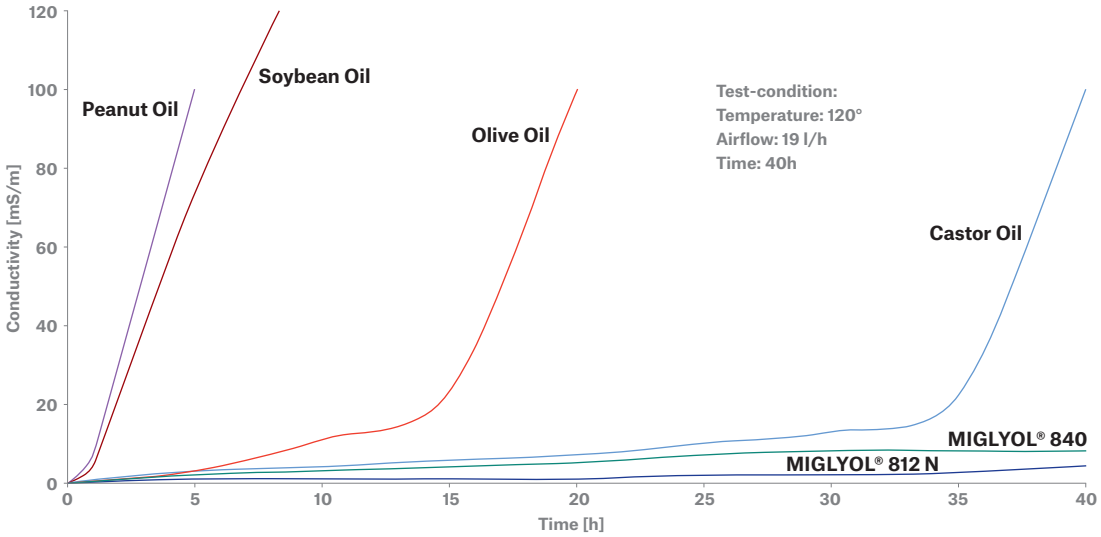
MIGLYOL® neutral oils are highly suitable carriers for poorly soluble APIs for use in injectable formulations. Because of their polarity, they exhibit superior solvent characteristics for some active drugs compared to hydrocarbons.

Stability testing on the RANCIMAT repeatedly shows that medium-chain triglycerides exhibit significant advantages with regard to oxidative stability compared to most other typically used pharmaceutical grades of vegetable oils.

MIGLYOL® 810 N and MIGLYOL® 812 N are medium spreading oils and differ in the ratio of C8/C10 fatty acids.

MIGLYOL® 840 is in comparison a higher spreading oil based on propylene glycol as the alcohol component that exhibits extremely low viscosity.

OXIDATION STABILITY WITH METROHM RANCIMAT TEST EQUIPMENT



The conductivity increases exponential when the natural content of antioxidants in vegetable oil is consumed and the capacity to resist autoxidation is exhausted

Additionally, the CEP and Type II DMF can also be referenced if the DRUG SUBSTANCE is used as an excipient for innovative, high-end injectable dosage forms.

RENEWABLE AND CONSISTENT

Our products are based on:

- High-quality vegetable-derived raw materials from approved suppliers that comply with tight specifications and a
- cGMP-compliant and solvent-free de-novo synthesis

This – together with the close monitoring of our manufacturing and purification process – results in products with very high batch-to-batch consistency and advantageous impurity profiles as an ideal basis for drug products with a long shelf life.

PROVEN PHARMACEUTICAL QUALITY

The MIGLYOL® lipid excipients are approved ingredients in injections and infusions:

- ✓ Narcotics (Propofol)
- ✓ Malaria (Artemether, Lumefantrine)
- ✓ Muscle relaxant (Etomidate)
- ✓ API-loaded microspheres (Exenatide)
- ✓ Veterinary injection suspension (Amoxicillin, Ceftiofur)
- ✓ Follicle Stimulating Hormones (Progesterone)
- ✓ GnRH Modulator (Triptorelin)
- ✓ Neuroleptics (Flupentixol)
- ✓ Benzodiazepines (Diazepam)

CLASSIFIED AND USED AS API FOR PARENTERAL NUTRITION

Parenteral applications require substances of highest quality standards. MIGLYOL® 812 N Drug Substance is manufactured specifically for use in parenteral nutrition. It has already been used in that route of administration for decades and is globally considered as the benchmark.

As a result of our tightly controlled manufacturing processes, we guarantee the first-class quality of MIGLYOL® 812 N Drug Substance: an excellent impurity profile, including a very low water level, is the basis for the safety and stability of the drug product formulation.

PRODUCT	CHEMICAL DESCRIPTION	LISTED IN	APPEARANCE	VISCOSITY mPa· s 20 ° C
MIGLYOL® 812 N Drug Substance	Triglycerides, Medium-Chain, MCT neutral oil (ratio C8:C10 ~ 60:40%)	Ph. Eur., USP–NF, JPE US DMF Type II, No. 27975 valid CEP	Almost colorless and odorless oily liquid	~ 30.0

MEDIUM CHAIN TRIGLYCERIDES IN LIPID EMULSIONS:

MCTs are highly effective energy carriers for clinical nutrition with MIGLYOL® 812 N Drug Substance. Supplying patients with quick energy through immediate metabolization without any risk of metabolites being deposited in fatty tissue or blood vessels.

PREMIUM QUALITY „MADE IN GERMANY“:

IOI Oleo constantly challenges the status quo to deliver products with the appropriate quality. In 2019, IOI Oleo completed the construction of a new building dedicated for filling API grade ester oils. Design and floor planning were completely in accordance with applicable pharma industry regulations and state-of-the-art standards. These include the requirement that only qualified and experienced employees are involved in the production process, following strict product safety and hygiene rules.

- ✓ The Witten production site is EU GMP-certified and US FDA cGMP inspected.
- ✓ Filling process: Class D cleanroom environment, fully automated procedures and microfiltration.

EXPERIENCED IN QUALITY AND REGULATORY AFFAIRS:

IOI is the holder of the first CEP (Certificate of Suitability) ever granted for a Medium Chain Triglyceride and has filed a Type II US-DMF.

Via the Letter of Access, you will be able to
- reduce efforts spent on regulatory affairs during dossier compilation and application,
- shorten your time to market,
- reduce regulatory efforts and cost during the commercial life cycle of the fully registered market authorization.

- ✓ Appropriate pharmaceutical cGMP standards
- ✓ Regular monitoring program including microbial and endotoxin testing
- ✓ Compendial compliance covering major global pharmacopoeia standards

Your various benefits and advantages at a glance:
IOI Oleo's MIGLYOL® range for application in injectable drug products provides you with additional value.

- ✓ Multi-compendial – Ph. Eur, USP-NF, JPE
- ✓ Well established and widely accepted by authorities.
- ✓ Reduced impurities for improved drug quality
- ✓ Renewable raw materials of vegetable origin
- ✓ Oxidative stable and long shelf life (at least 36 months)

- ✓ EU GMP-certified
- ✓ US FDA cGMP inspected
- ✓ ISO 9001 & ISO 45001
- ✓ Halal / Kosher
- ✓ EMAS
- ✓ RSPO SCCS

Leading global expert and innovator of functionalised ester-based lipids with added value for pharma solutions.

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