



EXCIPIENTS FOR PHARMACEUTICALS

SCOPE OF APPLICATION



IOI OLEOCHEMICAL

IOI Oleo GmbH
PHARMA

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Regulatory background for the IOI Oleo site in Witten:

EU GMP-certified

US FDA-approved

DIN ISO 9001/14001-certified

EMAS registered

CEP

Certificate of suitability to the monographs of
the European Pharmacopoeia, granted for MIGLYOL® 812 N

US Drug Master Files

Type II: MIGLYOL® 812 N

Type IV: MIGLYOL® 810 N/812 N, WITEPSOL®s



Injectables – IV, SC, and IM

C8/C10 triglycerides (MCT oils) and propylene glycol ester, used as a carrier:

MIGLYOL® 810 N

Medium-Chain Triglycerides (ratio ~ 70:30%)

MIGLYOL® 812 N

Medium-Chain Triglycerides (ratio ~ 60:40%)

MIGLYOL® 840

Propylene Glycol Dicaprylocaprate

Application examples:

- Narcotics (Propofol)
- Malaria (Artemether, Lumefantrin)
- Muscle relaxans (Etomidate)
- Veterinary injection suspension (Amoxicillin, Ceftiofur)



Injectables – enteral and parenteral nutrition

C8/C10 triglycerides (MCT oils)

MIGLYOL® 812 N – Medium-Chain Triglycerides
(ratio ~ 60:40%)

Dosage forms: enteral and parenteral nutrition

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

MIGLYOL® 812 N has been used in enteral and parenteral nutrition for decades. From a regulatory point of view, the ingredients in some of these formulations are classified as API.



Topical/dermal applications



Self-emulsifying ready-to-use cream base

O/W base **SOFTISAN® 601**

Suitable for the preparation of skin-compatible, wash-off O/W creams, exhibiting a water content of up to 65%. Non-sensitive to ion-active APIs.

Application examples:

Heparin and steroidal creams, wound care

Emulsifier O/W

IMWITOR® 372 P – Glyceryl Stearate Citrate

IMWITOR® 375 – Glyceryl Citrate/Lactate/Linoleate/Oleate



Powerful non-toxic emulsifiers, excellent compatibility with skin and mucosa

Application examples: antibacterial creams

IMWITOR® 960 K – self-emulsifying glyceryl monostearate emulsions with **IMWITOR® 960 K** are compatible with a wide range of APIs and therefore an excellent basis for stable formulations.

SOFTISAN® 154 – Hydrogenated Palm Oil

Triglyceride of blends of natural, saturated, even-numbered and unbranched vegetable fatty acids of mainly C16 and C18. It contains no additives, such as antioxidants or stabilizers.

Topical formulations



Emulsifier W/O

IMWITOR® 600 NON-GMP – Polyglyceryl-3 Polyricinoleate
Especially suitable for soft to low-viscosity W/O emulsions and lotions; excellent stability of formulations even with high water content.

Dosage forms:

enteral and parenteral nutrition

MIGLYOL® 812 N has been used in enteral and parenteral nutrition for decades.

From a regulatory point of view, in some of these formulations specific ingredients incl. **MIGLYOL® 812 N** are classified as API.

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

Topical formulations



Skin protection

SOFTIGEN® 701 – Glyceryl Ricinoleate

It is attracted to the adsorption sites on the skin's surface due to the free hydroxyl group. Therefore, it protects the skin from being attacked by damaging substances. After long-term use in pharmaceutical preparations and in an epicutaneous skin test, **SOFTIGEN® 701** showed excellent tolerability.

Penetration enhancer

IMWITOR® 742 – Glycerol Monocaprylocaprate, Type I

IMWITOR® 988 – Glycerol Monocaprylate, Type I

Several scientific tests illustrate their ability to enhance the skin penetration of poorly soluble APIs. Both excipients are used in various dosage forms in amounts of 3–15%, depending on the kind and amount of active substance.

Topical formulations



Oleogels for consistency regulation

MIGLYOL® Gel B

Manufactured by jellifying **MIGLYOL® 812 N** neutral oil, using an inorganic and chemically modified hectorite clay.

MIGLYOL® Gel T

W/O emulsions containing this oleogel reduce phase separation even after short heating up to approx. 90 °C.

MIGLYOL® Gel 840 B

Manufactured by jellifying **MIGLYOL® 840** oil with an inorganic chemically modified hectorite clay.

These specialties are recommended for use as consistency regulators in pharmaceutical preparations where it is important to maintain the viscosity over a wide temperature range (occlusion).

SOFTISAN® 649 – the compliant and modern alternative to lanolin

Applications

- Wound dressing
- Wound care (ointments, creams, lotions, emulsions)
- Protective baby skin treatment
- Ophthalmic formulations
- Nasal preparations
- Powder additive
- Transdermal drug delivery systems



Characteristics

- Based on pure vegetable and synthetic raw materials (Bis-Diglyceryl Polyacyladipate-2)
- Non-occlusive
- Superior adhesion to skin and mucosae
- Low water content < 0.25% (m/m)
- High water-binding capacity of more than 200% (m/m)
- Free from additives such as antioxidants, preservatives, or stabilizers



WITEPSOL® – well-established hard fats for suppository/ovule production



State-of-the-art production

- Production through de novo synthesis
- Modern Sandvik pastillation belt
- Clean room class D environment
- Automatic packing process
- Full GMP compliance



WITEPSOL® – well-established hard fats for suppository/ovule production

Our WITEPSOL® grades

- W Series (4 types)
- H Series (7 types)
- S Series (3 types)
- E Series (3 types)



GMP-certified production

- US: FDA-approved
- EU: GMP-certified

Expertise in hard fats for decades

- Production in Witten since the mid 1950s
- State-of-the-art production
- 7 different grades

Regulatory aspects

- US-DMF No. 420
- GRAS (CFR sect. 172.861)
- Ph. Eur, USP and JPE monograph compliance given for most WITEPSOL®s

Mucosa and skin protection



Rectal irritations caused by suppositories may be due to various reasons. The use of coarse crystalline substances or subsequent recrystallization on the surface of the suppositories as well as many plant extracts – e.g. Echinacea extract – can cause irritations of the rectal mucosa. Such irritations can be reduced by using certain **WITEPSOL®** grades (**WITEPSOL® H 19** and **WITEPSOL® S 58**). These hard fats contain our excipient **SOFTIGEN® 701**, which is able to protect the mucosa and also encapsulates the drug by forming a slight gel.

Therefore, these hard fat grades are especially recommended for use in hemorrhoidal suppository applications or for ovule usage.

Hard fats – application beyond suppositories

In addition to our **WITEPSOL®** types, we also offer **SOFTISAN® 378**, a fat with a consistency similar to natural lard. **SOFTISAN® 378** complies with the requirements of the Ph. Eur. monograph „Hard Fat“.

WITEPSOL®s and **SOFTISAN® 378** are used in pharmaceutical dosage forms such as

- chewable tablets, e.g. antacid formulations
- creams, e.g. formulations containing corticosteroids
- soft gel capsules, e.g. vitamin capsules, anti-cancer formulations.



Hot melt Coating

SOFTISAN® 154 – Hydrogenated Palm Oil

Triglyceride of blends of natural, saturated, even-numbered and unbranched vegetable fatty acids of mainly C16 and C18. Off-white to ivory-colored solid mass with a faint fatty odour.

SOFTISAN® 154 is characterized by its exceptional hardness at room temperature and its sharp melting range.

The small interval between melting point and solidification point allows rapid and economic processing.

DYNASAN® P 60 (F) – Hydrogenated Palm Oil

A white hydrogenated fat powder, based on palm oil, odorless and

with a neutral flavor. It contains no additives, such as antioxidants or stabilizers.

DYNASAN® 118 – Glyceryl Tristearate

A pure, monoacid triglyceride, white microfine powder, based on stearic acid of plant origin, odorless and tasteless. It contains no additives, such as antioxidants or stabilizers.

Application examples:

Taste masking for APIs with an unpleasant taste, e. g. acetylcysteine, coating to protect API from GI medium (enteric coating), e.g. Diclofenac, coating of granules, e.g. stick pack solutions.



Solid dosage forms



DYNASAN®s 110*, 112*, 114, 116, 118

These pure monoacid triglycerides are glycerin esters of selected saturated, even-numbered and unbranched single fatty acids of plant origin. They are free from antioxidants and other stabilizers.

Typical applications are in tablet production where the **DYNASAN®s** are used as lubricants and to increase the tablet fracture stability. Depending on the concentration, **DYNASAN®s** can also be used as a controlled release component.



Application examples:

Osteoporosis prophylaxis and supportive treatment, in tablet form. Treatment of colds and influenza, in hard capsules. For use in dosage forms such as SLN, SEDDS, SMEDDS, hot melt coating (taste masking), hot melt extrusion.

* Available on demand only, but can be offered in sample volumes.

Soft gel capsules



MIGLYOL® 812 N – Medium-Chain Triglycerides (ratio ~ 60:40%)
Due to the nature of the product, it acts as a low-viscosity carrier oil.

SOFTISAN® 378

Recommended for formulation that requires a more solid but still soft API-carrier. Blend of triglycerides, product meets the requirements of the current Ph. Eur. and USP-NF monographs “Hard Fat”.

IMWITOR® 742 – Glycerol Monocaprylocaprate, Type I

Acts as a solubilizer and penetration enhancer for poorly soluble drugs in oral administration forms.

Application examples:

Various formulations, e.g. treatment of chronic hand eczema, benign prostatic hyperplasia, HIV/antiretroviral, vitamins.

Veterinary formulations

Notes

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C8/C10 triglycerides (MCT oils)

MIGLYOL® 810 N – Medium-Chain Triglycerides
(ratio ~ 70:30%)

MIGLYOL® 812 N – Medium-Chain Triglycerides
(ratio ~ 60:40%)

Application examples:

Veterinary injection suspension (Amoxicillin, Ceftriaxone)

MIGLYOL® 840 – Propylene Glycol Dicaprylocaprate

Application examples:

Pour-on formulation for treatment against internal and external parasites (e.g. Ivermectin, Moxidectin)

Contact

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