IOI OLEOCHEMICAL

Engineered Lipid Excellence for

Topical Applications

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

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CONTENTS

Tried & Trusted – Quality & Innovation

At IOI Oleo GmbH, we empower the development of modern pharmaceutical topical formulations through our nature-based excipients. These ingredients combine proven functionality, regulatory compliance, and a pleasant sensory experience.

While localized drug delivery is well-established for acute conditions, patient adherence becomes especially critical in the treatment of chronic skin diseases. In such cases, formulation design, sensory attributes, and the origin of ingredients play a vital role in ensuring long-term compliance.[1]

Our brands – **IMWITOR®, MIGLYOL®, SOFTIGEN®, SOFTISAN®, DYNASAN®** and **WITEPSOL®** – stand for consistent quality, outstanding performance, and tangible benefits in the final formulation.

With a legacy dating back to the 1950s at the former Chemische Werke Witten, IOI Oleo GmbH has built a reputation for excellence in the production of high-purity, vegetable-based esters. These multifunctional ingredients serve as emollients, emulsifiers, and more—contributing directly to the quality and safety of pharmaceutical products.

Our commitment to purity, safety, and sustainability is reflected in our robust regulatory framework and certifications. We operate under cGMP regulations at our Witten facility, which is regularly inspected by the German Health Authority. Our products are derived from up to 100% renewable, plant-based raw materials.

As a co-founder of the Roundtable on Sustainable Palm Oil (RSPO), IOI Group integrates sustainability into every aspect of its operations. In addition to RSPO certification, we comply with a wide range of international standards, including:

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

[1] Topical drug delivery systems in dermatology: a review of patient adherence issues, 2012

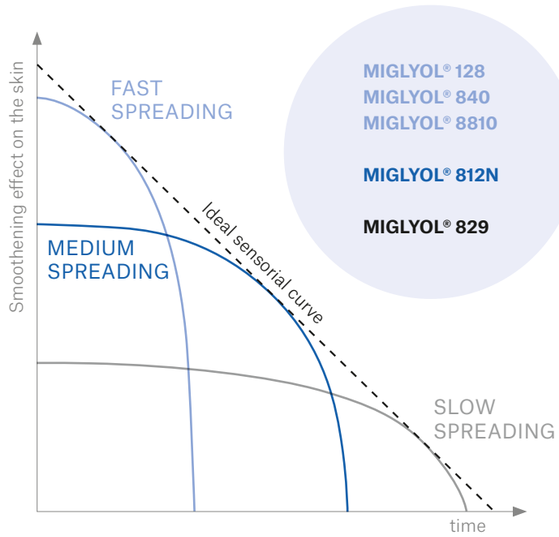
Emollients

The MIGLYOL® emollients are widely used in the pharma industry as drug carriers; they possess superior solvent characteristics for lipophilic actives and high stability against stress factors and ageing.

These vegetable-based emollients are neutral oils that offer a wide range of different sensory profiles from light silicone-like to rich and caring. Refatting, even superfatting and improvement of skin moisturization are achieved without occlusion and risk for maceration.

IDEAL SENSORIAL CURVE

The MIGLYOL® emollient range offers formulators the possibility of creating the ideal sensory experience thanks to the spectrum of spreading behaviour provided.



CONSUMER BENEFITS:

- ✓ Sensory profile according to consumer needs
- ✓ Silicone-like skin feel possible
- ✓ Light skin feel possible
- ✓ Caring and rich skin feel possible

PREMIUM EXCIPIENTS FOR SUPERIOR STABILITY AND PURITY

High-quality raw materials and cGMP certified production result in excipients that provide excellent stability in color and low impurity profiles. MIGLYOL® Emollients are non-oxidizing and practically water-free.

MIGLYOL® 128

Chemical description/monograph name:
Cocoyl Caprylocaprate
Listed in: Ph. Eur.
Appearance: Slightly yellowish oily liquid
Viscosity mPa· s 20 °C: ~ 11

This low-viscosity, non-polar emollient and refatting agent can be considered a true vegetable alternative for light petrochemical emollients or silicones (e.g. D5)

It provides an extremely light skin feel due to its fast spreading properties, facilitating uniform distribution and optimal absorption.

MIGLYOL® 810 N (C8/C10 ratio ~ 70:30%)

MIGLYOL® 812 N (C8/C10 ratio ~ 60:40%)

Chemical description/monograph name:
Medium-Chain Triglyceride
Listed in: Ph. Eur., USP–NF, Ch.P., US DMF Type IV
Appearance: Almost colorless and odorless oily liquid
Viscosity mPa· s 20 °C: ~ 30

Neutral oils, stable, used as penetration enhancers, drug carriers and emollients as well as solvents for dermal application.

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® 829

Chemical description/monograph name:
Caprylic/Capric/Succinic Triglyceride
Appearance: Light yellowish oily liquid
Viscosity mPa· s 20 °C: ~ 260

Neutral, stable oil of high viscosity, low-spreading superfatting agent which gives formulations a long-lasting, rich skin feel.

With a density of ~ 1,01 g/ml, it acts as an emulsion stabilizer and allows inverted emulsions.

MIGLYOL® 840

Chemical description/monograph name:
Propylene Glycol Dicaprylocaprate
Listed in: Ph. Eur., USP–NF
Appearance: Almost colorless and odorless oily liquid
Viscosity mPa· s 20 °C: ~ 11

A polar, high spreading emollient with low viscosity. It leaves a light, non-oily, smooth and velvety skin sensation similar to low molecular weight silicone oils. Furthermore, it shows excellent dispersing and solvent properties.

MIGLYOL® 8810

Chemical description/monograph name:
Butylene Glycol Dicaprylate/Dicaprate
Appearance: Colorless oily liquid
Viscosity mPa· s 20 °C: ~ 13

Polar, fast-spreading light emollient with excellent solvent characteristics.

It is a completely saturated, neutral oil, exhibiting a low allergenic potential and is non-sensitizing.

Skin Care applications: as a skin conditioning agent protecting the skin from external stress.

Special Cream Bases

SOFTISAN® 378

Chemical description/monograph name:
Hard Fat, Adeps solidus

Listed in: Ph. Eur., USP–NF, Ch.P.

Appearance: White to ivory colored solid fat

Melting Point °C: ~ 38

A refatting, nourishing emollient, drug carrier and consistency regulator that is ideal for all topical application forms, e.g. ointments, creams, lotions and pastes.

It imparts structure and is therefore recommended for formulations that require a more solid but still soft API-carrier. Particularly for semi-solid dosage forms the use of SOFTISAN® 378 offers numerous advantages as it melts quickly on the skin and has a spreading cascade comparable to that of a mixture of different oils. Its film-forming properties ensure a light, non-tacky caring effect.

While the typical dosage in emulsion formulations is 15%, already the use of 2% SOFTISAN® 378 can change the sensorial properties significantly.

Based on saturated even-numbered, unbranched natural fatty acids of vegetable origin, the superior oxidation stability and product uniformity can be guaranteed.

SOFTISAN® 601

Chemical description/monograph name:
Glycerides, C12-C18 Mono- and Di-, Glyceryl Stearate, PEG-4, Polyoxyethylene (25) Cetyl Stearyl Ether, PEG-32, PEG-6, Medium-Chain Triglycerides, Glyceryl Ricinoleate (stabilized)

Appearance: Off-white soft pastilles

Melting Point °C: 40 – 45

- Ready-to-use water-free O/W cream base
- Non-sensitive to ion-active APIs like Ketoprofen, Paracetamol, Miconazole, etc.
- Forms stable emulsions e.g. for Heparin and steroidal creams, wound care applications.

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

SOFTISAN® 649

Chemical description/monograph name:
Bis-Diglyceryl Polyacyladipate-2

Appearance: Off-white opaque mass

Melting Point °C: ~ 35

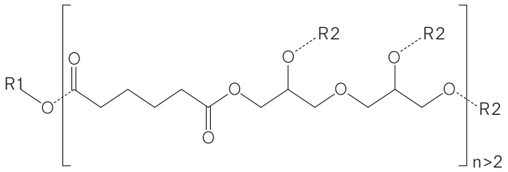
This compliant and modern alternative to lanolin is used in wound dressings and wound care products like creams and ointments due to its high water uptake of more than 200% and exceptional adhesion to skin and mucous membranes.

Film-former that helps to improve the skin barrier by reducing transepidermal water loss. Especially suitable for wound dressing systems and irritated skin.

SOFTISAN® 649 shows the same properties as Lanolin, without affecting the color and the smell of a formulation in a negative way. Applicable for hot and cold processes and is miscible with all fats and oils.

RECOMMENDED CONCENTRATION:
0.5 - 5%

CHEMICAL STRUCTURE:



R1 = diglycerol
R2 = adipic acid, 12-hydroxystearic acid, isostearic acid, caprylic acid, capric acid, stearic acid

Water-free Formulations – In vivo Studies

A significant proportion of APIs under clinical development exhibit poor aqueous solubility and may be sensitive to hydrolysis or adverse reactions-triggered by impurities. Thus, water-free formulations offer a technically sound approach to mitigate these risks while simultaneously minimizing the need for preservatives or other stabilizers.

While petroleum-based formulations are well established in topical applications, they present limitations in terms of occlusivity and patient acceptability, particularly in chronic use.

By combining IOI Oleo's plant-based excipients, you can develop anhydrous systems with petrolatum-like texture, optimized viscosity, and a modern sensory profile. These formulations allow precise control over skin feel and melting behavior—key parameters for therapeutic efficacy and patient acceptance.

SOFTISAN® 378 – a proven base for water-free formulations
With its unique physico-chemical properties, SOFTISAN® 378 is an excellent starting point for developing water-free formulation concepts.

The results of the in vivo study conducted with dry skin panelists are compelling:

- Improve skin moisturization by 40-60%
- Significantly increase skin softness
- The formulations did not show a significant influence of transepidermal water loss and therefore will not contribute to skin occlusion or increase the risk of maceration.
- Study participants positively assess the skin feel and user experience

Formulation and study details are available upon request.

Emulsifiers

EMULSIFIER O/W

IMWITOR® 372 P

Chemical description/monograph name:
Glyceryl Stearate Citrate
Appearance: Light brownish flakes
HLB value: 10 – 12
Melting Point °C: ~ 62

Oil-soluble O/W emulsifier, partly neutralized and anionic. Viscosity enhancing, builds structures similar to phospholipids, stable emulsions at pH range 4 to 7.
100% natural, leaving a smooth and silky skin feel. This hot processable emulsifier can be combined with a large number of co-emulsifiers.

RECOMMENDED CONCENTRATION:
2 – 4% as main emulsifier
0.5 – 2.0% as co-emulsifier

IMWITOR® 375

Chemical description/monograph name:
Glyceryl Citrate/Lactate/Linoleate/Oleate
Appearance: Yellow to amber-colored, honey-texture
HLB value: 10 – 12

Oil-soluble O/W emulsifier, partly neutralized and anionic. Similar to phospholipids for stable emulsions at pH range 4 to 7.
100% natural, sunflower-based. It is cold-processable and can emulsify up to 30% of oil phase.
Already at 1% it forms thin and light emulsions with a soft, velvety touch and creams just by adding co-emulsifier, fatty alcohol and a thickening agent.
Excellent compatibility with skin and mucosa, suitable for preparation of SMEDDS.

RECOMMENDED CONCENTRATION:
1 – 3% as main emulsifier
0.5 – 2% as co-emulsifier or solubilizer in anhydrous systems

IMWITOR® 960 K

Chemical description/monograph name:
Glyceryl Monostearate, self-Emulsifying
Listed in: BP
Appearance: Flakes
HLB value: 9 – 12
Content of monoglycerides: >= 30%
Melting Point °C: 56 – 61

This self-emulsifying glyceryl stearate quality is a classic anionic emulsion stabilizer for rich creams and ointments. Works best at neutral pH, is compatible with a wide range of APIs and therefore an excellent basis for stable formulations.

RECOMMENDED CONCENTRATION:
2 to 7%

IMWITOR® 491

Chemical description/monograph name:
Glyceryl Monostearate
Listed in: USP–NF
Appearance: Off-white powder
HLB value: ~ 4
Content of monoglycerides: > 90%
Melting Point °C: 66 – 77

O/W co-emulsifier, emulsion stabilizer, stiffening and dispersing agent. IMWITOR® 491 enhances the consistency of O/W emulsions.

RECOMMENDED CONCENTRATION:
1 to 3%

IMWITOR® 900 (F) P

Chemical description/monograph name:
Glycerol Monostearate 40 – 55%, Type I

Listed in: Ph. Eur., USP–NF

Appearance: Off-white powder

HLB value: ~ 3

Content of monoglycerides: 40 – 55%

Melting Point °C: 54 – 64

Emulsion stabilizer, dispersing agent and consistency enhancer in O/W emulsions.

RECOMMENDED CONCENTRATION:
1 to 3%

IMWITOR® 900 K

Chemical description/monograph name:
Glycerol Monostearate 40 – 55%, Type II

Listed in: Ph. Eur., USP–NF

Appearance: Off-white powder

HLB value: ~ 3

Content of monoglycerides: 40 – 55%

Melting Point °C: 54 – 64

Emulsion stabilizer, dispersing agent and consistency enhancer in O/W emulsions.

RECOMMENDED CONCENTRATION:
1 to 3%

EMULSIFIER W/O

IMWITOR® 600

Chemical description/monograph name:
Polyglyceryl-3 Polyricinoleate

Appearance: Amber colored liquid

HLB value: ~ 4

IMWITOR® 600 is a powerful W/O emulsifier with excellent stability even with a high water content.

It is especially suitable for soft or low viscous W/O emulsions with a non-greasy, pleasant skin feel.

RECOMMENDED CONCENTRATION:
2 to 4%

Nanoemulsions

NANOEMULSIONS AS A FORMULATION APPROACH FOR TOPICALS

IMWITOR® 375 based nanoemulsions have shown to outperform commercial benchmarks and other advanced delivery systems in terms of penetration depth, total amount of active delivered and sustained efficacy.

In partnership with IOI Oleo GmbH, two nanoemulsion systems (W/O/W and O/W) with IMWITOR® 375 have been developed. In Franz cell tests, both systems showed reproducible results in terms of good bioavailability as well as optimized penetration depth and speed compared to existing topical formulations under development.

CASE STUDY I: HYDROCORTISONE FROM W/O/W NANOEMULSION

- 0.5 % 3H-hydrocortisone
- Application: 10 µl/cm² over 24 h
- Franz diffusion cell, 3 benchmarks (commercial gel, aqueous solution, liposome) vs. IMWITOR® 375 based nanoemulsion
  - IMWITOR® 375 based nanoemulsion delivers 3-4x as much active ingredient into the subcutis as the benchmarks
  - IMWITOR® 375 based nanoemulsion delivers 2-3x as much active ingredient into the acceptor fluid of the Franz diffusion cell as the benchmarks

CASE STUDY II: IBUPROFEN FROM O/W NANOEMULSION

- 0.5 % 3H-ibuprofen
- Application: 10 µl/cm² over 24 h
- Franz diffusion cell, 2 benchmarks (commercial gel, non-commercialized gel) vs. IMWITOR® 375 based nanoemulsion
  - IMWITOR® 375 based nanoemulsion delivers the highest amount of active ingredients to the skin
  - IMWITOR® 375 based nanoemulsion delivers 3-4x as much active ingredient into the acceptor fluid of the Franz diffusion cell as both benchmarks

With these study results, IMWITOR® 375 based nanoemulsions promise far better bioavailability with constant active ingredient use on the one hand or, on the other hand, enable reduced quantities of active ingredients to be used while maintaining the same bioavailability. This can have advantages for the cost structure, formulation economy and expected side effects or incompatibilities.

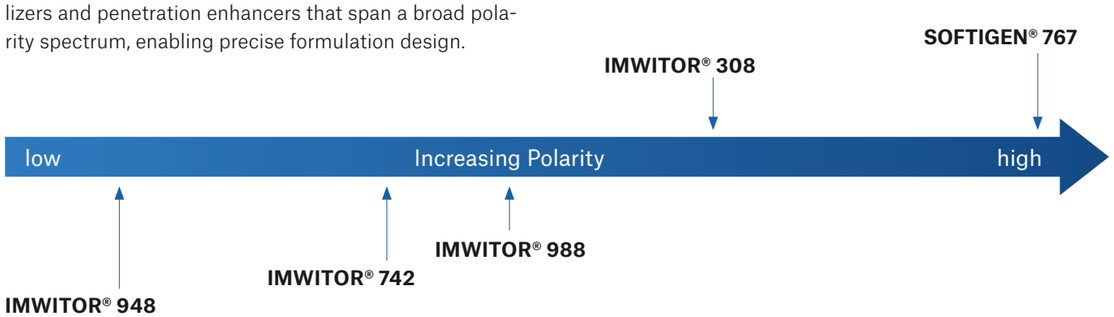
Study details on other active ingredients are avaible, too.

KEY FEATURES OF THE NANOEMULSIONS BASED ON IMWITOR® 375

- ✓ High loadings of up to 12 % active ingredient
- ✓ Significant improvement in solubility compared to non-encapsulated active ingredient presentation, e.g. tocopherol @ 100 mg/ml
- ✓ PSD: 120-250 nm and smaller
- ✓ PDI: <0.2
- ✓ Green chemistry based on plant-based raw materials such as sunflower, sugar beet, sugar cane and rapeseed
- ✓ Confirmed uses in semi-solid and liquid dosage forms
- ✓ Patentable

Solubilizers & Penetration Enhancers

The effectiveness of a topical formulation often depends on the compatibility between active ingredients and excipients—particularly in terms of polarity. At IOI Oleo GmbH, we offer a comprehensive portfolio of solubilizers and penetration enhancers that span a broad polarity spectrum, enabling precise formulation design.



Our excipients are fully miscible with one another, allowing formulators to fine-tune key parameters such as melting point, solubility, bioavailability, polarity, and texture. This flexibility supports the development of optimized delivery systems for both hydrophilic and lipophilic actives.

Whether you are formulating self-emulsifying drug delivery systems (SEDDS), improving dermal absorption, or enhancing the sensory profile of your product, our solubilizers and enhancers provide reliable performance and formulation versatility.

SOFTIGEN® 767

Chemical description/monograph name:
Macrogol 6 Glycerol Caprylocaprate

Listed in: Ph. Eur.

Appearance: Clear liquid

HLB value: ~ 14

A mild cleansing agent with excellent refatting and skin caring characteristics. Suitable for clear, low-viscous, water-based formulations.

Suitable for use in the preparation of SEDDS. Solubilizer for drugs, wetting and refatting agent. Soluble in water and hydrophilic oils (e.g. MCT oil).
Even on eczematous skin its toleration is exceptional, and it is therefore used for psoriasis treatment.
SOFTIGEN® 767 is a good solubilizer, e.g. for essential oils and volatile crystalline substances.
SOFTIGEN® 767 is also a very popular mild cleansing agent in wet wipes.

RECOMMENDED CONCENTRATION:
Leave-on: 0.5 to 5.0%
Rinse-off: 2 – 10% according to application

IMWITOR® 308

Chemical description/monograph name:
Glycerol Monocaprylate, Type II

Listed in: Ph. Eur., USP–NF

Appearance: Crystalline solid

Content of monoglycerides: >= 80%

Melting Point °C: 27 – 33

Co-emulsifier and penetration enhancer.
Up to 10% water can be dissolved to clear solution.
It can be used in emulsions, surfactant-based or hydroalcoholic formulations. Its versatile properties including refatting and wetting performance make it a multifunctional ingredient.

IMWITOR® 308 is known to exhibit bacteriostatic properties and boosts preservative efficacy.

IMWITOR® 742

Chemical description/monograph name:
Glycerol Monocaprylocaprate, Type I

Listed in: Ph. Eur., USP–NF, Ch.P.

Appearance: Liquid to pasty/solid

HLB value: ~ 3 – 4

Content of monoglycerides: 45 – 75%

Melting Point °C: ~ 25

Co-Emulsifier and solubilizer for poorly water-soluble drugs that fall into class II and IV of the Biopharmaceutical Classification System (BCS).
Defoaming agent
Water-soluble up to 10%

Also available as CEP (Certificate of Suitability) grade

IMWITOR® 948

Chemical description/monograph name:
Glycerol Mono-Oleate 40

Listed in: Ph. Eur., USP–NF

Appearance: Yellowish, liquid to pasty

HLB value: ~ 3

Content of monoglycerides: ~ 44%

Suitable for W/O and O/W emulsions.
Improves penetration of emollients into the stratum corneum and has water-binding capacity, forms gels in excess water. Used in rinse-off products, glycerol monooleate reduces skin roughness caused by surfactants.

Solubilizer for lipophilic APIs and bioavailability enhancer. Oily vehicle containing long-chain fatty acids (C18:2) for Lipid Formulation Classification System Type I (oily), Type II (SEDDS), and Type III (SMEDDS), associated with lymphatic absorption. Oily vehicle for topical formulations. Safety of use is inferred from GRAS status and precedence of use in approved pharmaceutical products.

RECOMMENDED CONCENTRATION:
1 to 3%

IMWITOR® 988

Chemical description/monograph name:
Glycerol Monocaprylate, Type I

Listed in: Ph. Eur., USP–NF

Appearance: Clear, oily liquid

Content of monoglycerides: 45 – 75%

Melting Point °C: ~ 23

Co-Emulsifier and bioavailability booster for poorly water-soluble drugs.

RECOMMENDED CONCENTRATION:
3 – 15%

Viscosity Regulators

Thickening of oil phases can be necessary to give the finished form the required consistency and skin feel. All recommended products are characterized by their neutral smell and are successfully used in topical forms such as lotions and creams as body-imparting and structure forming ingredients.

DYNASAN® 118

Chemical description/monograph name:
Glyceryl Tristearate

Listed in: USP–NF

Appearance: Off-white, flakes and microfine powder

Melting Point °C: 69 – 73

DYNASAN® 114

Chemical description/monograph name:
Trimyristin

Appearance: Off-white, flakes

Melting Point °C: 55 – 60

SOFTISAN® 154

Chemical description/monograph name:
Hydrogenated Palm Oil

Appearance: Off-white, flakes

Melting Point °C: 53 – 58

WITEPSOL® E 85

Chemical description/monograph name:
Hard Fat, Adeps solidus

Listed in: Ph. Eur., USP–NF, Ch.P.

Appearance: Pastilles

Melting Point °C: 42 – 44

WITEPSOL® H 15

Chemical description/monograph name:
Hard Fat, Adeps solidus

Listed in: Ph. Eur., USP–NF, Ch.P.

Appearance: Pastilles

Melting Point °C: 33.5 – 35.5

A MATTER CLOSE TO OUR HEART - SUSTAINABILITY LEADS THE WAY

IOI Corporation Berhad (IOI) has set itself the goal of being a frontrunner in both the production and the procurement of sustainable palm oil. We are also committed to the cultivation of sustainable oil palm plantations and the implementation of a responsible global palm oil supply chain. The sustainability value is firmly embedded into the IOI vision, Core Values, policy statements and working practices at all of our sites. We make continuous progress in our efforts to achieve our ambitious goals while at the same time analyzing and sustainably aligning our processes.

Sustainability in practice: Our projects
We strive to strengthen and implement our activities on a sustainable basis. Several national and international initiatives contribute to reducing CO_2 emissions in our operations and limiting the impact of our products on the environment as well as preserving or promoting biodiversity. Because this is the only way we can reach Net Zero by 2040, achieve sustainable business practices and, furthermore, make a positive contribution to biodiversity. But for us sustainability also means the well-being of society. We have implemented codes that apply for all interested parties, whether internal or external.
We support non-profit organisations with the aim of making the world a better place for us all.

Sustainable sourcing and carbon footprint awareness are core values we have defined for our company and implemented in our daily activities.

- Up to 100 % vegetable, renewable raw materials
- Option for RSPO Mass Balance certified supply model
- ISO 14001 certified
- Ecovadis Sustainability Rating: Gold medal
- EMAS conform
- Associate Member of the PSCI

Of course, sustainability is a complex topic that drives our society and is equally central to our mission at IOI Oleo GmbH.

If you would like further information in this respect relating to our products, their manufacture and activities at our sites, please get in touch directly with your favourite contact person!

We look forward to hearing from you.