



IOI OLEOCHEMICAL

Essentials for Capsules

CAPSULE INGREDIENTS FOR ALL REGULATORY SCOPES

At IOI Oleo, we combine the expertise of two crucial fields: the pharmaceutical and nutritional sectors. This enables us to seamlessly offer our partners the best selection of ingredients for every regulatory scope. Whether it's about developing medicinal capsules with the highest efficacy and safety or nutritional supplements that promote health and well-being – we are your reliable partner. Discover how our integrated expertise can elevate your products to the next level.

OUR PRODUCTS

...combine

- plant origin
- effectiveness
- multifunctionality
- compliance

... enable ingredient-reduced yet consistent formulations

TOGETHER WE COVER

- functional food
- nutritional supplements (though as health food)
- nutraceuticals
- pharmaceutical dosage forms
- specialty diets
- metabolic deficiencies

Capsules rank among the most popular dosage forms after tablets. Experts predict that this dosage form will maintain double-digit growth rates throughout the next decade. Its popularity can be attributed to its numerous advantages.

Consumers appreciate the fact that capsules are easier to take and unpleasant sensory properties of active ingredients and excipients are not perceived. But it is above all for the formulator and during production that the full potential of capsules is revealed.

Capsules can be dosed effortlessly and precisely, are inexpensive to produce, durable and space-saving. They also enable gentle processing of sensitive ingredients. A fundamental distinction must be made between different capsule types:



HARD CAPSULES

Hard capsules are preferred for solid fillings such as powders and granules. They consist of two prefabricated halves that are pushed over each other; fine grooves prevent the filling from escaping and ensure a tight seal.



SOFT CAPSULES

Soft capsules consist of 2 halves that are tightly connected by a weld seam. They are particularly suitable for oils, emulsions and preparations from a liquid to pasty consistency.



CHEWABLE CAPSULES

This dosage form was specially developed for chewing and therefore allows larger sizes. Even products that pose a sensory challenge, such as fish oil, can be given a pleasing taste through flavouring.

NUTRITION



HACCP

**STATE-OF-THE-ART
DE-NOVO
SYNTHESIZED
FUNCTIONAL
LIPIDS**

**ALL
PRODUCTS
ARE VEGAN**

**MADE IN
GERMANY**

**COMPLIANT
WITH THE HIGHEST
REGULATORY
STANDARDS**

**CLEAN ROOM
PRODUCTION**

**FDA
APPROVED**



PHARMA

**GMP
CERTIFIED**



FOCUS ON REALLY NEEDED INGREDIENTS IN CAPSULES

Following the general trend towards low-complexity formulation development, the biggest advantage for for-
mulators and producers of capsules is to focus on the excipients really needed for efficient delivery of the active
ingredient(s). IOI Oleo GmbH’s portfolio offers a range of functional de novo synthesized lipids that can be used
in all capsule types.

- Broad range of properties and textures
- Dietary benefits due to special metabolism of medium-chain lipids
- Products are of plant origin
- Poorly soluble active ingredients of BCS classification II + IV can be successfully administered with the help of our products, as it is possible to use them in special active ingredient release systems such as SEDDS

Did you know?

All palm-based products are also available under RSPO-certified supply chain models!



PRODUCT	COMPENDIAL TITLE/ CHEMICAL DESCRIPTION	PRIMARY SCOPE OF USE	MELTING POINT (°C)	CONSISTENCY AT ROOM TEMPERATURE	MONOESTER CONTENT (%)	HYDROXYL VALUE (MG KOH/G)	FUNCTION
SOFTISAN® 378	Hard Fat	Pharma	~ 39	soft-creamy paste	< 1	< 50	Carrier
IMWITOR® 308	Glycerol monocaprylate, type II	Pharma	27-33	solid	> 80	450 - 550	Carrier, Solubilizer & Bioavailability booster
IMWITOR® 742	Glycerol monocaprylocaprate, type I (available with CEP support)	Pharma	~ 25	pasty to solid	45 - 75	315 - 380	Carrier, Solubilizer & Bioavailability booster
IMWITOR® 988	Glycerol monocaprylate, type I	Pharma	~ 23	liquid	45 - 75	315 - 380	Carrier, Solubilizer & Bioavailability booster
MIGLYOL® 812 N	Triglycerides, medium-chain	Pharma	< 0	liquid	< 1	<10	Carrier, Lubricant
MIGLYOL® 810 N	Triglycerides, medium-chain	Pharma	< 0	liquid	< 1	<10	Carrier, Lubricant
WITARIX® MCT 60/40	Caprylic/Capric triglyceride	Nutraceutical	< 0	liquid	< 0	<10	Carrier, Glazing and release agent, Lubricant
WITARIX® MCT 70/30	Caprylic/Capric triglyceride	Nutraceutical	< 0	liquid	< 0	<10	Carrier, Glazing and release agent, Lubricant
WITARIX® MCT C8	Caprylic triglyceride	Nutraceutical	< 0	liquid	< 0	<10	Carrier, Glazing and release agent, Lubricant
WITARIX® MCT powder AC8CN	Caprylic triglyceride and gum acacia	Nutraceutical	< 0	powder	< 0	<10	Solution for an easy-to-handle powder, with a high oil load and good solubility

For consumer-centric claims WITARIX® products are available with Coconut origin!

FUNCTIONAL BENEFITS

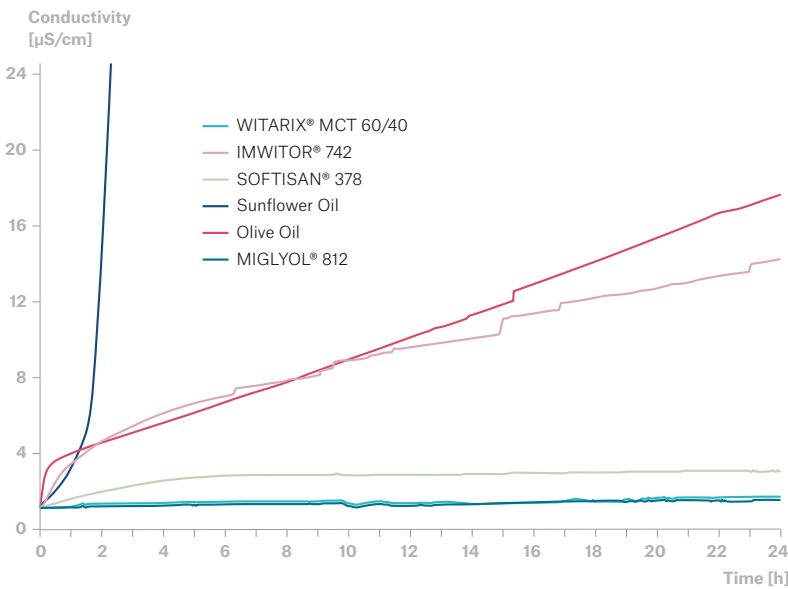
STABILITY

Rancimat testing

A well-established method for the determination of oxidation stability in fats, oils and fat-containing preparations. The received data is an indicator for raw material stability and potential shelf life of finished products. The accelerated ageing under standardized lab conditions allows us to extrapolate the negative effects of exposure to light, oxygen and temperature over time.

Conductivity measurement:

Conductivity in native/pristine lipids is typically very low to nil. Stress factors can change the chemical composition of lipids to impact colour, taste, smell and texture. This phenomenon of rancidification is also called autoxidation. Autoxidation leads to conductivity increases.

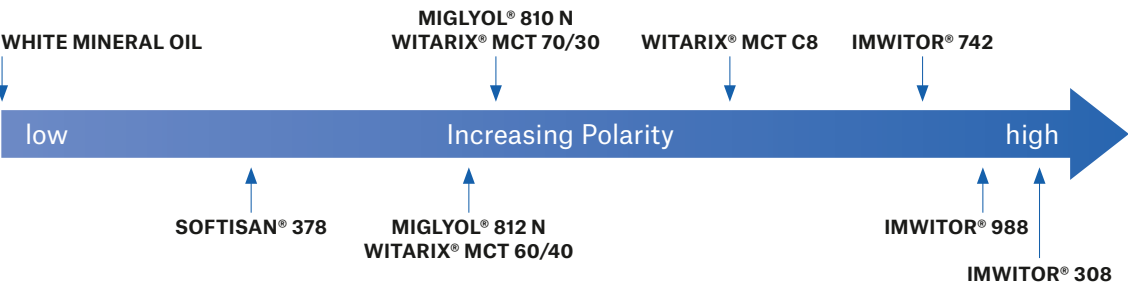


CARRIER OIL	CONDUCTIVITY	
	at t ₀ [µS/cm]	after 24h [µS/cm]
Sunflower Oil, refined	1,0	400
Olive Oil, native	1,1	36,3
IMWITOR® 742	1,0	35
SOFTISAN® 378	1,1	3,3
WITARIX® MCT 60/40	1,1	1,8
MIGLYOL® 812 N	1,0	2,1

POLARITY

The suitability of particular raw materials for a formulation depends on various factors, one of which is the anticipated polarity of the ingredients.

Polarity is determined by the chemical composition, including the degree of esterification (inversely related to the hydroxyl value) and the fatty acid composition. Higher hydroxyl values increase relative hydrophilicity and polarity. Materials containing medium-chain fatty acids tend to exhibit higher polarity, whereas those with long chain fatty acids typically display lower polarity.



All these products are fully miscible with each other, so that melting point, bioavailability, solubilization capacity, polarity or texture can be specifically adjusted.

BIOAVAILABILITY

Medium-chain partial glycerides (MCPGs) and medium-chain triglycerides (MCTs) share a range of critical properties making them highly relevant as carriers and bioavailability enhancers for use in nutraceutical and pharmaceutical forms. Key characteristics include:

Solubilization Capacity:

- Medium-chain fatty acids in these compounds solubilize lipophilic drugs, forming micelles in the intestinal lumen that incorporate poorly soluble actives, increasing their absorption.
- Their strong affinity for lipophilic molecules allows them to solubilize and stabilize many active pharmaceutical ingredients (APIs), enhancing bioavailability.

Enhanced Permeability and Transport:

- The surfactant properties of these compounds enhance intestinal epithelium permeability, improving transport across the intestinal barrier.

Particle Dispersion:

- Both medium chain partial glycerides and MCTs disperse poorly soluble actives into smaller particles, increasing the surface area available for absorption in the intestine.

Rapid Absorption:

- MCTs and medium-chain partial glycerides are rapidly absorbed directly into the portal circulation without the need for bile salts or pancreatic enzymes, leading to faster drug delivery and improved efficacy.

Formulation Versatility:

- Their low viscosity and low melting points make them suitable for liquid and semi-solid dosage forms, facilitating easy dispersion and processing as capsule fillings.

Compatibility:

- MCTs and MCPGs are compatible with a wide range of ingredients and actives, easily incorporated into various formulations without causing compatibility issues.

Taste and Odour Neutrality:

- MCTs are relatively neutral in taste and odour, making them ideal for oral dosage forms and improving patient compliance by masking unpleasant tastes or odours of certain APIs.
- MCPGs have a characteristic, scratchy or bitter taste. Use in capsules, however, addresses this issue perfectly.

Safety and Metabolization:

- MCTs and MCPGs are readily metabolized into ketone bodies as a source of energy. They are generally regarded as safe (GRAS) for use in pharmaceutical and nutraceutical formulations.

The following active ingredients are delivered in capsules with our excipients:

- Hormones
- Cannabinoids
- Protease Inhibitors
- Alpha Blockers
- Androgen Blockers
- Tyrosine Kinase Inhibitors
- Vitamins & Vitamin Derivatives

OUR PRODUCTION SITES

With the production capacities at our sites in Wittenberge and Witten, IOI Oleo GmbH is the leading supplier of medium-chain triglycerides (MCTs) and related products in Europe. Reliable quality and purity from batch to batch are the result of strong synthesis competence, the use of high-quality raw materials sourced exclusively from approved suppliers and tightly controlled manufacturing procedures.

WITTEN

From a former soap factory to a modern production facility for oleochemical specialties based on plant-derived fats and oils: This is the success story of our site in Witten in the south-western part of the Ruhr district. We have already been meeting the high GMP standards (Good Manufacturing Practice) of the pharmaceutical industry since 2005 with our production processes. This also includes regularly reoccurring inspections by the local German health authority and US FDA to confirm the GMP compliance of our activities.

Products for capsules from the Witten site:

- **IMWITOR® 742**
- **IMWITOR® 988**
- **MIGLYOL® 810 N**
- **MIGLYOL® 812 N**
- **SOFTISAN® 378**

- ✓ EU GMP/ API production on site
- ✓ US FDA cGMP approved
- ✓ ISO 9001, ISO 45001
- ✓ EMAS
- ✓ RSPO SCCS
- ✓ HACCP
- ✓ Halal
- ✓ Kosher



- ✓ ISO 50001
- ✓ FSSC 22000
- ✓ RSPO SCCS
- ✓ Halal
- ✓ Kosher



WITTENBERGE

At our manufacturing site in the Prignitz region, we produce oleochemical solutions based on plant-derived medium-chain triglycerides (MCTs).

With a broad MCT portfolio, we are able to respond flexibly to customer and industry requirements, including specific feedstock preferences and certification options.

The site has state-of-the-art esterification plants with short-path distillation capability that allows us to produce certain specialties with high purity.

Products for capsules from the Wittenberge site:

- **IMWITOR® 308**
- **WITARIX® MCT 60/40**
- **WITARIX® MCT powder AC8CN**
- **WITARIX® MCT 70/30**
- **WITARIX® MCT C8**



OUR COMMITMENT IN PRACTICE

IOI Corporation Berhad (IOI) is a long-standing member of the Roundtable on Sustainable Palm Oil (RSPO) and operates certified palm oil production facilities and plantations.

The company has established policies, management systems and programmes related to environmental, social and supply chain topics across its operations. These principles are reflected in IOI's vision, core values, policy statements and operational practices. IOI regularly reviews and further develops its processes and management systems as part of its ongoing business activities.

Our Projects and Initiatives

Across our operations, we carry out projects and programmes addressing topics such as greenhouse gas emissions, resource efficiency, supply chain management and biodiversity-related measures.

Our approach is supported by policies, standards and codes of conduct that apply across the organisation and to relevant business partners.

In addition, we participate in community engagement activities and support selected non-profit organisations.

At IOI Oleo GmbH, we continuously work on topics related to our products, manufacturing processes and operational activities

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.

- ✓ Depending on the product, raw materials can be derived from up to 100% plant-based sources
- ✓ RSPO Mass Balance certified material available on request
- ✓ ISO 14001 certified
- ✓ EMAS conform
- ✓ Associate Member of the PSCI





IOI Oleo GmbH
Hamburg, Germany
+49 40 28 00 31-0
info@ioioleo.de
www.ioioleo.de

Disclaimer

IOI Oleo GmbH makes no representations or warranties, neither express nor implied, on the suitability for specific medical device or pharmaceutical applications of the products to which the information refers. In particular, the customer is fully responsible to determine end-use suitability and is not exempted from the obligation to conduct careful inspection and testing of incoming goods.

Important notice

All trademarks displayed in this brochure are the property of IOI Oleochemical's group of companies except as otherwise marked. Users of this brochure are not permitted to use these trademarks without the prior written consent of their proprietor. All rights are reserved. Reference to trademarks used by other companies is neither a recommendation, nor should it give the impression that products of other companies cannot be used.