



IOI OLEOCHEMICAL

PHARMA

MIGLYOL[®] 812 N & IMWITOR[®] 742

PRODUCT SPOTLIGHTS



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IMWITOR® 742

Chemical Description / Monograph Name:

- Glyceryl Mono and Dicaprylocapapate according to Ch.P.;
Registration number: F20220000443
- Glycerol Monocaprylocaprate, Type I, according to Ph. Eur.
also available as CEP-grade: CEP 2021-199
- Glyceryl Mono- and Dicaprylocaprate, USP-NF

Description:

IMWITOR® 742 is a partial glyceride of fully saturated caprylic and capric acid, based on plant-based raw materials, containing not less than 65 % of surface-active mono- and diglycerides.

Typical dosing recommendations between 3-15 %



FUNCTIONALITIES

- Drug Carrier
- Solubilizer
- Bioavailability Booster
- Co-Emulsifier O/W
- Defoamer



TYPICAL USES / DOSAGE FORMS

- Capsules
- Topicals
- Aerosols



KEY FEATURES

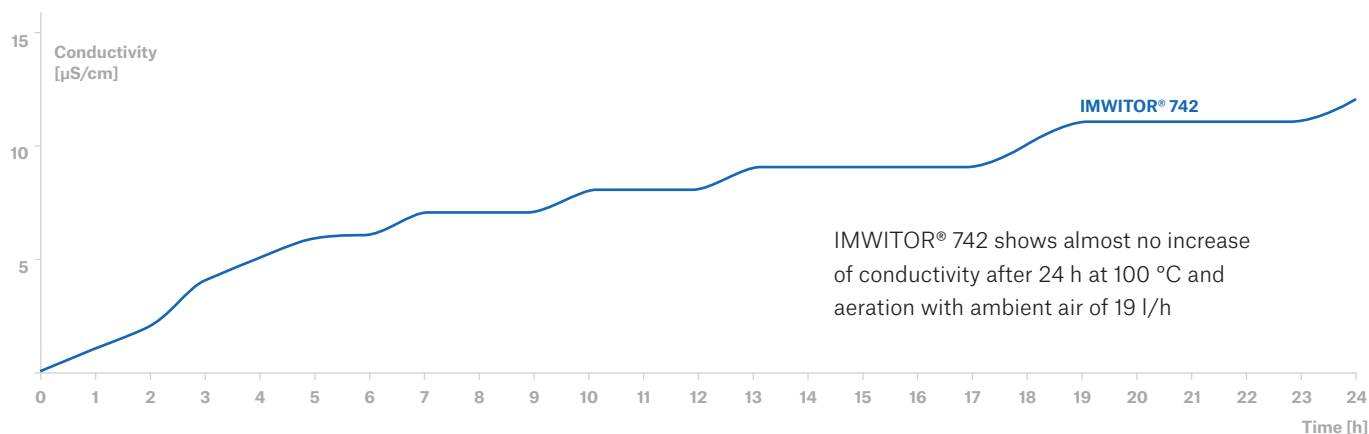
- Co-Emulsifier and Bioavailability Booster
for poorly water-soluble drugs
- Defoaming Agent
- Can incorporate up to 10% of water
- Very stable against oxidation



PHYSICO-CHEMICAL PROPERTIES / APPEARANCE

- Liquid to pasty-solid
- Melting point °C: ~ 25
- HLB value: 5 – 6

IMWITOR® 742 - OXIDATIVE STABILITY



FUNCTIONS	ROUTES OF ADMINISTRATION	ESTABLISHED DOSAGE FORMS	API
Bioavailability Booster	Oral	Softgel Capsules	Tipranavir, Dutasteride
Defoaming Agent		Tablets	
Solubilizer		I.e. Capsules	
Plasticizer		Tablet Coatings	
Active Booster / Carrier		Sublingual Spray	Glycerolnitrate
Absorption / Penetration Enhancer	Topicals	Creams and Lotions	
Co-Emulsifier			

The bioavailability enhancing property of IMWITOR® 742:

- Content of medium-chain fatty acids has the ability to solubilize lipophilic compounds
- In the intestinal lumen IMWITOR® 742 can form micelles incorporating poorly soluble actives, increasing their absorption concentration
- Enhanced permeability of the intestinal epithelium; due to their surfactant property, transport across intestinal barrier is improved
- Lymphatic absorption: Medium chain fatty acids are known to be preferentially absorbed into the lymphatic systems, bypassing the liver and potentially increasing bioavailability
- IMWITOR® 742 may increase the surface area available for absorption by dispersing the poorly soluble active into smaller particles and droplets, supporting the interaction with absorptive surfaces in the intestine

TYPICAL PROPERTIES AND VALUES

TESTS	VALUES	TYPICAL VALUES	UNITS
Acid value	max. 3.0	0.8	mg KOH/g
Saponification value	250 - 280	267	mg KOH/g
Water content	max. 0.5	0.13	%
Monoglycerides	45.0 - 75.0	58	%
Diglycerides	20.0 - 50.0	35	%
Free glycerol	max. 3.0	0.5	%
Hydroxyl value	315 - 380	364	mg KOH/g
Iodine value	max. 1	0.18	g I2/100 g



AVAILABLE PACKAGING

- 25 kg net, HDPE container
- 190 kg net, drum



SHELF LIFE

36 Months after date of production in originally sealed and well-closed packing units at or below room temperature

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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.



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MIGLYOL® 812 N

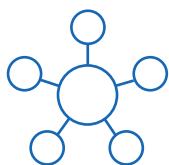
Chemical Description / Monograph Name:

- Ch.P.: Medium-Chain Triglycerides, NMPA Registration: F20230000391
- Ph. Eur. / B.P. (current version): Triglycerides, Medium-Chain
- USP (current version): Medium-Chain Triglycerides
- MIGLYOL® 812 N also available as API Grade: NMPA registration Y20190009085; CEP R1-CEP 2012-410

Description:

MIGLYOL® 812 N is a triglyceride ester of saturated caprylic and capric fatty acids, made from plant-based raw materials.

MIGLYOL® 812 N is a clear, virtually colorless, low viscosity liquid with a neutral odor and taste.



FUNCTIONALITIES

- Drug Carrier
- Emollient
- Solubilizer
- Lubricant



KEY FEATURES

- Neutral, Penetration Enhancer, Drug Carrier and Emollient
- Made from renewable, vegetable raw materials
- Excellent stability against thermal and oxidative stress
- Low impurity profile for improved drug quality, also available as API-Grade



TYPICAL USES / DOSAGE FORMS

- Injectables
- Topicals
- Capsules
- Oral liquids

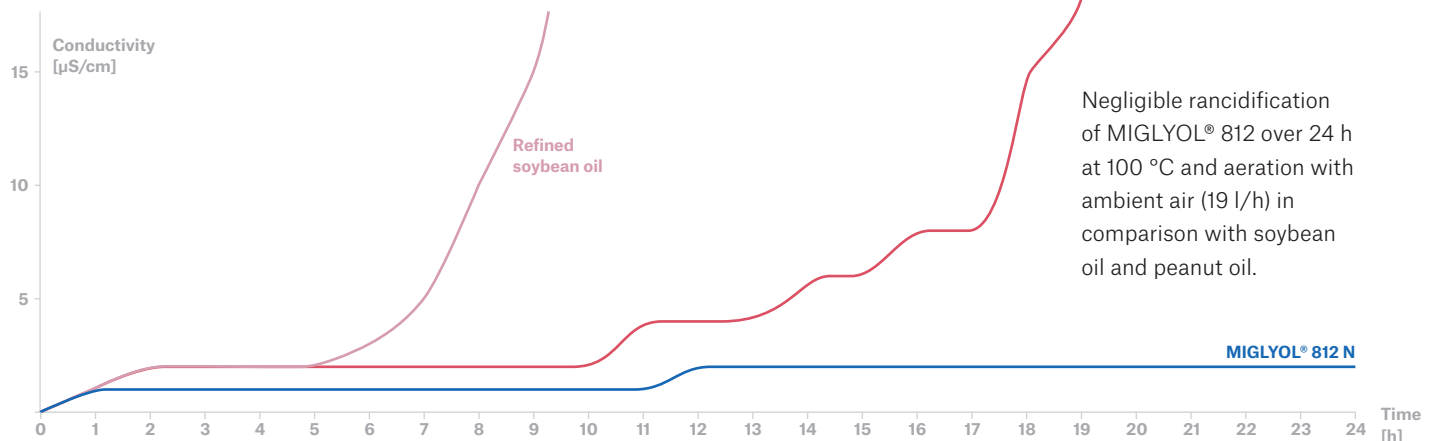


PHYSICO-CHEMICAL PROPERTIES / APPEARANCE

- Oily liquid
- Viscosity mPa*s 20 °C: ~30

FUNCTIONS	ROUTES OF ADMINISTRATION	ESTABLISHED DOSAGE FORMS	API	
API Carrier / Solubilizer	Oral	Syrup / Suspension (also vet.)	Penicillin	
		Oral Solution		
		Aerosol	Glycerolnitrate	
		Lozenges	Amylmetacresol	
Absorption Promoter		Oral	Oral Drops, Soft Gelatine Capsules (also vet.)	Lubiproston, Dutasteride, Calcitriol, Vitamin D3, Dronabinol, Simeticone, Calcidiol monohydrate, Isotretinoin, Nintedanib, Paricalcitol, Testosterone, Alitretinoin, Eprinomectin
Carrier / Solvent (Lipophilic Vitamins)				
Nutritional Supplements			Oral Solution	Ciprofloxacin, Terbinafine
Lubricant			Tablets, Dragees	Alendronate, Colecalciferol
Softener / Plasticizer			Chewing Tablets (also vet.)	Raltegravir, Afoxolaner
Lubricant / Dispergent Agent		Vaginal	Soft Gel Pessary	Clotrimazole
	Rectal	Suppository	Bismuth, Zinc Oxide, Paracetamol	
Moisturizer, API Carrier	Ophthalmics	Eye Drops	Azithromycin	
		Eye Gel	Carbomer	
API Carrier / Solvent	Parenteral Application	Injectables, i.v., i.m. and s.c. (also vet.)	Ampicillin, Amoxicillin, Artemether, Enrofloxacin, Buparvaquone, Ceftiofur, Cefalexin, Cefquinom, Perphenazine, Flupenthixol, Diazepam, Propofol, Etomidat, Cephapirin, Progesterone, Etofenamat	
Active Pharmaceutical Ingredient				Parenteral Nutrition
Skin Caring Lipid (absorption-promoting, spreadability, scale-detaching, keratin softening)	Topicals	Creams, Lotions, Ointments, Gel, Emulsion	Tapinarof, Hydrocortisone, Capsaicin, Ibuprofen, Pimecrolimus, Azelaic Acid, Mupirocin, Permethrin, Thioconazol, Flufenaminic Acid, Mometasonfuroat, Dexpanthenol, Bufexamac, Lidocaine, Tretinoin, Campher, Levomenthol	
		Spreading Agent	Veterinary Pour-on / Spot-on Solution	Imidacloprid, Permethrin, Dicyclanil, Moxidectin
Emollient				

MIGLYOL® 812 N - OXIDATIVE STABILITY



Major considerations for using MCTs as drug carriers:

Solubilization capacity: MCTs are highly lipophilic compounds, meaning they have a strong affinity for other lipophilic molecules, including many APIs. This property allows MCTs to solubilize and stabilize lipophilic APIs, enhancing their bioavailability.

Low viscosity: MCTs typically have a low viscosity compared to other oils and fats. This characteristic makes them suitable for formulating liquid and semi-solid dosage forms such as oral solutions, suspensions, emulsions and topical creams, where easy dispersion and administration are desired.

Rapid absorption: MCTs are metabolized differently than long chain triglycerides (LCTs). They are absorbed directly into the portal circulation without the need for bile salts or pancreatic enzymes. This rapid absorption can lead to faster delivery of the API to systemic circulation, potentially improving the onset of action and overall efficacy of the pharmaceutical product.

Stability: MCTs are generally stable under various processing and storage conditions. They have a low susceptibility to oxidation, which helps maintain the stability and shelf-life of pharmaceutical formulations containing MCTs as carriers for APIs.

Compatibility: MCTs are compatible with a wide range of pharmaceutical excipients and APIs. They can be easily incorporated into various formulations without causing compatibility issues or affecting the stability of other ingredients.

Taste and odor neutrality: MCTs are relatively neutral in taste and odor, which makes them suitable for use in oral dosage forms where palatability is important. They can mask the unpleasant taste or odor of certain APIs, improving patient acceptance and compliance.

Biodegradability and safety: MCTs are metabolized by the body into ketone bodies or utilized as a source of energy, making them readily biodegradable. They are generally regarded as safe (GRAS) for use in pharmaceutical formulations and have a low risk of adverse effects when administered orally or topically.

TYPICAL PROPERTIES AND VALUES

TESTS	VALUES	TYPICAL VALUES	UNITS
Acid value	max. 0.2	0.02	mg KOH/g
Hydroxyl value	max. 10	3	mg KOH/g
Water	max. 0.2	0.02	%
Viscosity at 20 °C	25 - 33	30	mPa·s
Color	max. 60	24	APHA
Caprylic acid (C _{8:0})	50.0 - 80.0	58	%
Capric acid (C _{10:0})	20.0 - 50.0	41	%
Content (C ₈ /C ₁₀)	min. 95.0	99	%



AVAILABLE PACKAGING

- 25 kg net, HDPE containers
- 190 kg net, drum
- 900 kg net, IBC



SHELF LIFE

36 Months after date of production in originally sealed and well-closed packing units at or below room temperature