

PHARMA

# WE ADD EXCELLENCE TO EXCIPLENTS

IOI Oleo GmbH



### For lipid-based excipients and active pharmaceutical ingredients "Made in Germany" – you can rely on us.

Decades of experience and expertise shape today's quality of our specialty products and drive new product developments and operational excellence.

As a result, our brand names are considered all over the globe as the benchmark in parenteral nutrition as in well as topical, oral and rectal applications and animal health.

Quality, compliance, functionality, and technical support are the cornerstones of the day-to-day cooperation with customers and partners.

Our dedication and strict commitment to the highest product purity and safety are reflected every day in the effort of our employees and the pursuit of continuous improvement.

The repeated confirmation of our Good Manufacturing Practices (GMP) by the responsible competent German authority and the US FDA acknowledge our intention to deliver quality leadership to the healthcare industry.

- **DYNASAN**<sup>®</sup> Monoacid triglycerides for various applications
- Simultor Functionalized lipids for drug delivery systems
- **MIGLYOL**<sup>®</sup> MCT oil and related C8-C10 fatty esters
- SOFTIGEN<sup>®</sup> Liquid solubilizer for lipophilic substances
- SOFTISAN<sup>®</sup> Specialties for topical and oral application forms
- **WITEPSOL**<sup>®</sup> Hard fats for suppositories and ovules

Lipid-based excipients made in Germany, manufactured in our EU GMP-certified and US FDA-approved production facility

#### Abbreviations:

CEP = Certificate of Suitability to the monographs of the European Pharmacopoeia

CFR = Code of Federal Regulations

DMF = Drug Master File

JPE = Japanese pharmaceutical excipients

Ph. Eur. = European Pharmacopoeia

USP-NF = United States Pharmacopeia-National Formulary

BP = British Pharmacopoeia

FCC = Food Chemicals Codex

HLB = Hydrophilic-lipophilic balance

GRAS = Generally Recognized As Safe



DYNASAN®	4
IMWITOR <sup>®</sup>	6
MIGLYOL®	8
SOFTIGEN®	10
SOFTISAN®	11
WITEPSOL®	12
Register of chemical/	
monograph names	16

## **DYNASAN**<sup>®</sup> Monoacid triglycerides for various applications



High Melting point lipids for use in modified or sustained release in oral solid dosage matrices.

#### Product name: DYNASAN® 114

**Chemical description/monograph name:** Trimyristin

Melting point °C: 55-60

Hydroxyl value mg KOH/g: max. 10

**Properties and applications:** Effective lubricant for tablets/ capsules.

Product name: DYNASAN® 116

**Chemical description/monograph name:** Tripalmitin

Melting point °C: 63-68

Hydroxyl value mg KOH/g: max. 10

**Properties and applications:** Effective lubricant for tablets/ capsules. Hot melt extrusion, hot melt coating, solid lipid nanoparticles.

#### Product name: DYNASAN® 118

Chemical description/monograph name: Glyceryl tristearate Listed in: USP-NF, GRAS acc. to CFR 21 sec. 172.811

Melting point °C: 69-73

Hydroxyl value mg KOH/g: max. 5

**Properties and applications:** Effective lubricant for tablets/ capsules and enhances the tablet fracture stability. Hot melt extrusion, hot melt coating, solid lipid nanoparticles.

### **IMWITOR**<sup>®</sup> Functionalized lipids for drug delivery systems

The IMWITOR® family of products comprises specialty lipids that have a backbone that is only partially esterified. The free hydroxyl groups contribute to the hydrophilic properties, thus resulting in surface activity and excellent solvent characteristics for many poorly soluble drugs.

#### Product name: IMWITOR® 308

Chemical description/monograph name: Glycerol monocaprylate, type II Listed in: Ph. Eur., USP-NF Additional quality information: NON-GMP Appearance: Crystalline solid Melting point °C: 27-33 Content of monoglycerides: >= 80% Properties and applications: Co-Emulsifier, excellent antibacterial properties.

#### Product name: IMWITOR® 372 P

Chemical description/monograph name: Glyceryl stearate citrate Appearance: Light-brownish flakes HLB value: 10-12 Melting point °C: ~ 62 Properties and applications: Oil-soluble O/W emulsifier, partly neutralized and anionic. Similar to lecithin for stable emulsions at pH range 4 to 7.

#### Product name: IMWITOR® 375

Chemical description/monograph name: Glyceryl citrate/lactate/linoleate/oleate

Appearance: Yellow to brownish sticky liquid

HLB value: 10-12

**Properties and applications:** Suitable for use in the preparation of SMEDDS. Oil-soluble O/W emulsifier, partly neutralized and anionic. Similar to lecithin for stable emulsions at pH range 4 to 7.

#### Product name: IMWITOR® 491

### Chemical description/monograph name: Glyceryl monostearate Listed in: USP-NF Appearance: Off-white powder HLB value: ~ 4

Melting point °C: 66-77

**Content of monoglycerides:** > 90%

**Properties and applications:** Lipophilic matrix for oral solid dosage forms (granulation, hot melt technique). Used as tablet lubricant, O/W co-emulsifier, emulsion stabilizer, stiffening and dispersing agent for pigments.

#### Product name: IMWITOR® 600

Chemical description/monograph name: Polyglyceryl-3 polyricinoleate

Appearance: Yellow to brownish liquid

HLB value: ~ 4 Properties and applications: FCC-compliant W/O emulsifier for systems of low viscosity.

#### Product name: IMWITOR® 742

#### Chemical description/monograph name:

Glycerol monocaprylocaprate, type I

Listed in: Ph. Eur., USP-NF

Appearance: Liquid to pasty/solid

Melting point °C: ~ 25

#### Content of monoglycerides: 45-75%

**Properties and applications:** Penetration enhancer, solvent, defoaming agent in effervescent tablets, capsule filling mass.

#### Product name: IMWITOR® 900 (F) P

Chemical description/monograph name:

Glycerol monostearate 40–55%, type I

Listed in: Ph. Eur., USP-NF

Appearance: Off-white powder

Melting point °C: 54-64

Content of monoglycerides: 40-55%

#### HLB value: ~ 3

**Properties and applications:** Lipophilic matrix for oral solid dosage forms (granulation, hot melt technique). O/W emulsifier used as tablet lubricant, emulsion stabilizer, dispersing agent for pigments and for sustained release.

#### Product name: IMWITOR® 900 K

Chemical description/monograph name:

Glycerol monostearate 40-55%, Type II

Listed in: Ph. Eur., USP-NF

Appearance: Off-white powder

Melting point °C: 54-64

Content of monoglycerides: 40–55%

HLB value: ~ 3

**Properties and applications:** Lipophilic matrix for oral solid dosage forms (granulation, hot melt technique). O/W emulsifier used as tablet lubricant, emulsion stabilizer, dispersing agent for pigments and for sustained release.

#### Product name: IMWITOR® 948

Chemical description/monograph name: Glycerol mono-oleate Listed in: Ph. Eur., USP-NF Appearance: Yellowish, liquid to pasty

Content of monoglycerides: 32–52%

**Properties and applications:** O/W stabilizer, forms gels in excess water. Unsaturated partial glyceride, contains an antioxidant.

#### Product name: IMWITOR® 960 K

Chemical description/monograph name: Glyceryl monostearate, self-emulsifying Listed in: BP Appearance: Flakes Melting point °C: 56-61 Content of monoglycerides: >= 30% HLB value: 9-12 Properties and applications: Self-emulsifying GMS for dermal use

#### Product name: IMWITOR® 988

Chemical description/monograph name: Glycerol monocaprylate, type I Listed in: Ph. Eur., USP-NF Appearance: Clear, oily liquid Melting point °C: ~ 23.0 Content of monoglycerides: 45-75% Properties and applications: Penetration enhancer, solvent.

### MIGLYOL<sup>®</sup> MCT oil and related C8-C10 fatty esters



Liquid lipids are neutral oils for a wide spectrum of pharmaceutical applications. They possess superior solvent characteristics for lipophilic actives, an advantageous dietary profile, and high stability against stress factors and ageing.

#### Product name: MIGLYOL® 128

#### Chemical description/monograph name: Cocoyl caprylocaprate Listed in: Ph. Eur. Additional quality information: NON-GMP Appearance: Slightly yellowish oily liquid Viscosity mPa·s 20 °C: ~ 11.0 Properties and applications: Fast spreading non-polar emollient and refatting agent. It leaves a non-oily skin feel.

Product name: MIGLYOL® 810 N

#### Chemical description/monograph name:

Triglyceride, medium-chain / MCT neutral oil (ratio ~ 70:30%) Listed in: Ph. Eur., USP-NF, JPE, US DMF Type IV, No. 800 Appearance: Almost colorless and odorless oily liquid Viscosity mPa· s 20 °C: ~ 28.0

**Properties and applications:** Neutral, stable oil, penetration enhancer, drug carrier, solvent, for oral and dermal formulation.

#### Product name: MIGLYOL® 812 N Drug Substance

#### Chemical description/monograph name:

Triglyceride, medium-chain / MCT neutral oil (ratio ~ 60:40%) Listed in: Ph. Eur., USP-NF, JPE, CEP R0-CEP 2012-410-Rev 01, US DMF Type II, No. 27975

Appearance: Almost colorless and odorless oily liquid

Viscosity mPa·s 20 °C: ~ 30.0

**Properties and applications:** Lipid component in parenteral nutrition. Neutral, stable, solubilizer and carrier for oil-soluble actives.

#### Product name: MIGLYOL® 812 N Excipient

#### Chemical description/monograph name:

Triglyceride, medium-chain / MCT neutral oil (ratio ~ 60:40%) Listed in: Ph. Eur., USP-NF, JPE, US DMF Type IV, No. 800 Appearance: Almost colorless and odorless oily liquid Viscosity mPa· s 20 °C: ~ 30.0

**Properties and applications:** Neutral, stable oil, penetration enhancer, drug carrier, solvent, for oral and dermal formulation.

### Product name: MIGLYOL® 829

Chemical description/monograph name: Caprylic/capric/succinic triglyceride Appearance: Light yellowish oily liquid

Viscosity mPa· s 20 °C: ~ 260.0

**Properties and applications:** Neutral, stable oil of high viscosity and with a density of ~ 1.01, based on MCT and succinic acid. Superfatting agent and emulsion stabilizer.

Product name: 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: ~ 11.0 Properties and applications: Oil component, high spreading emollient with low viscosity.

Product name: MIGLYOL® 8810

Chemical description/monograph name: Butylene glycol dicaprylate/dicaprate Additional quality information: NON-GMP

 $\label{eq:product} \textbf{Appearance:} \ \textbf{Colorless oil of low viscosity}$ 

Viscosity mPa· s 20 °C: ~ 13.0

**Properties and applications:** Completely saturated, nonoxidizing neutral oil, exhibiting a low allergenic potential and it is non-sensitizing. It is used in topical application systems (ointments and creams) for psoriasis treatment. Readily absorbent, scale detaching, and keratin softening.

### **SOFTIGEN**<sup>®</sup> Liquid solubilizer for lipophilic substances



Fatty acid esters, further modified or compounded, help in creating specific pharmaceutical formulations.

#### Product name: SOFTIGEN® 767

Chemical description/monograph name: Macrogol 6 glycerol caprylocaprate Listed in: Ph. Eur.

Appearance: Clear liquid

HLB value: ~ 14

Properties and applications: 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).

#### Product name: SOFTISAN® 154

Chemical description/monograph name: Hydrogenated palm oil Melting point °C: 53-58

Hydroxyl value mg KOH/g: max. 10

Properties and applications: Solid lipid with sharp melting range, acts as viscosity regulator and is suitable for hot melt coating.

#### Product name: SOFTISAN® 378

#### Chemical description/monograph name:

Hard fat, Adeps solidus

Listed in: Ph. Eur., USP-NF

Melting point °C: ~ 38

Hydroxyl value mg KOH/g: 7-17

Properties and applications: Hard fat with softer consistency, similar to natural lard, but stable, odorless, emollient in creams, capsule filling mass.

#### Product name: 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

Properties and applications: Water-free self-emulsifying system, ready-to-use O/W cream base, suitable for processing a variety of pharmaceutical active ingredients.

### SOFTISAN® Specialties for topical and oral application forms

Product name: SOFTISAN® 649

Chemical description/monograph name: Bis-diglyceryl polyacyladipate-2 Appearance: Off-white opaque mass

Melting point °C: ~ 35

Properties and applications: Semi-solid lanolin substitute, adhesive to skin and wet mucous membranes, suitable for wound dressing systems and irritated skin, non-occlusive.

### WITEPSOL<sup>®</sup> Hard fats for suppositories and ovules



Apart from suppository manufacturing, solid triglycerides (hard fats) are used as carriers in capsule fillings, implants, ointments, creams, and in dental products. They also act as a surface treatment and binder in tablets. Solid triglycerides are manufactured through direct esterification of glycerol with defined fatty acid blends and, therefore, have precise properties regarding Melting point hydrophilicity (hydroxyl value) and consistency.

#### Product name: WITEPSOL® H 5

#### Chemical description/monograph name: Hard fat, Adeps solidus Listed in: Ph. Eur., USP-NF, JPE, US DMF No. 420 Melting point °C: 34.0-36.0 Hydroxyl value mg KOH/g: max. 5

#### Product name: WITEPSOL® H 12

Chemical description/monograph name: Hard fat, Adeps solidus Listed in: Ph. Eur., USP-NF, JPE, US DMF No. 420 Melting point °C: 32.0-33.5 Hydroxyl value mg KOH/g: 5-15

#### Product name: WITEPSOL® H 15

Chemical description/monograph name: Hard fat, Adeps solidus Listed in: Ph. Eur., USP-NF, JPE, US DMF No. 420 Melting point °C: 33.5-35.5 Hydroxyl value mg KOH/g: 5-15

#### Product name: WITEPSOL® H 19

Chemical description/monograph name: Hard fat + glyceryl ricinoleate (stabilized) Melting point °C: 33.5-35.5 Hydroxyl value mg KOH/g: 20-30

#### Product name: WITEPSOL® H 32

Chemical description/monograph name: Hard fat, Adeps solidus Listed in: Ph. Eur., USP-NF, JPE, US DMF No. 420 Melting point °C: 31.0-33.0 Hydroxyl value mg KOH/g: max. 3

#### Product name: WITEPSOL® H 35

Chemical description/monograph name: Hard fat, Adeps solidus Listed in: Ph. Eur., USP-NF, JPE, US DMF No. 420 Melting point °C: 33.5-35.5 Hydroxyl value mg KOH/g: max. 3

Product name: WITEPSOL® H 37

#### Chemical description/monograph name:

Hard fat, Adeps solidus Listed in: Ph. Eur., USP-NF, JPE, US DMF No. 420 Melting point °C: 36.0-38.0 Hydroxyl value mg KOH/g: max. 3

**Properties and applications:** WITEPSOL® products of series H (except H 19) are hard fats with hydroxyl values up to 15. They mostly consist of triglycerides with a portion of, at most, 15% diglycerides and not more than 1% monoglycerides. They are characterized by a very small gap between the melting and solidification temperatures, have only a minor tendency to the post-hardening phenomenon (maximum 1.5 °C), and can be processed both with automatic casting machines and, on a small scale, using the cream melting process (precrystallization) at casting temperatures around the stated melting point. Shock cooling should be avoided.

This series of grades also includes compounds having hydroxyl values (HV) between 0 and 5, which avoid interactions between the free OH groups and acidic active compounds (ASS, diclofenac, etc.). Suppository hard fats have commonly a low content of medium-chain fatty acids (C8/C10) whereas WITEPSOL® H32 and H 35 are adjusted to be softer.

### WITEPSOL<sup>®</sup> Hard fats for suppositories and ovules

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Product name: WITEPSOL® W 25

Chemical description/monograph name: Hard fat, Adeps solidus Listed in: Ph. Eur., USP-NF, JPE, US DMF No. 420 Melting point °C: 33.5-35.5 Hydroxyl value mg KOH/g: 20-30

#### Product name: WITEPSOL® W 32

Chemical description/monograph name: Hard fat, Adeps solidus Listed in: Ph. Eur., USP-NF, JPE, US DMF No. 420 Melting point °C: 32.0-33.5 Hydroxyl value mg KOH/g: 40-50

#### Product name: WITEPSOL® W 35

Chemical description/monograph name: Hard fat, Adeps solidus Listed in: Ph. Eur., USP-NF, JPE, US DMF No. 420 Melting point °C: 33.5-35.5 Hydroxyl value mg KOH/g: 40-50

#### Product name: WITEPSOL® W 45

Chemical description/monograph name: Hard fat, Adeps solidus Listed in: Ph. Eur., USP-NF, JPE, US DMF No. 420 Melting point °C: 33.5-35.5 Hydroxyl value mg KOH/g: 40-50

**Properties and applications:** WITEPSOL® products of series W are hard fats with hydroxyl values of 20–50. They consist of a mixture of triglycerides (65–80%), diglycerides (10–35%), and monoglycerides (1–5%). As a result of their composition, these WITEPSOL® grades have a larger gap between melting and solidification points, they are less sensitive to shock cooling (more elastic), solidify more slowly, and can be readily processed both with automatic machines and with small-scale equipment. The partial glyceride content also slows down the sedimentation of solids and promotes the absorption of less readily absorbable active compounds.

#### Product name: WITEPSOL® E 75

Chemical description/monograph name: Hard fat + beeswax Listed in: US DMF No. 420 Solidification Point °C: 34.0-36.5 Hydroxyl value mg KOH/g: max. 15 WITEPSOL® E 75 additionally contains beeswax (cera alba).

#### Product name: WITEPSOL® E 76

Chemical description/monograph name: Hard fat, Adeps solidus Listed in: Ph. Eur., USP-NF, JPE, US DMF No. 420 Melting point °C: 37.0-39.0 Hydroxyl value mg KOH/g: 30-40

#### Product name: WITEPSOL® E 85

Chemical description/monograph name: Hard fat, Adeps solidus Listed in: Ph. Eur., USP-NF, JPE, US DMF No. 420 Melting point °C: 42.0-44.0 Hydroxyl value mg KOH/g: 5-15

**Properties and applications:** WITEPSOL® products of series E are hard fat compounds having a Melting point above body temperature. They are used if active compounds lower the Melting point of the main hard fat because of their fat solubility. They are characterized by their Melting point and hydroxyl value.

#### Product name: WITEPSOL® S 51

Chemical description/monograph name: Hard fat + polyoxyethylene (25) cetyl/stearyl ether + glyceryl ricinoleate (stabilized) Listed in: US DMF No. 420

Melting point °C: 30.0-32.0

Hydroxyl value mg KOH/g: 55-70

#### Product name: WITEPSOL® S 55

Chemical description/monograph name: Hard fat + polyoxyethylene (25) cetyl/stearyl ether + beeswax Listed in: US DMF No. 420

Solidification Point °C: 28.0-33.0

Hydroxyl value mg KOH/g: 50-65

#### Product name: WITEPSOL® S 58

Chemical description/monograph name: Hard fat + polyoxyethylene (25) cetyl/stearyl ether + glyceryl ricinoleate (stabilized) Listed in: US DMF No. 420 Melting point °C: 31.5–33.0 Hydroxyl value mg KOH/g: 60–73

**Properties and applications:** WITEPSOL® products of series S are special grades that contain particular auxiliaries in addition to the hard fat of pharmacopoeias. They are used for the preparation of vaginal and rectal forms of medicines, which require better wetting of mucous membranes and enhanced dispersibility and are intended to promote absorption. Besides other ingredients like beeswax or glyceryl ricinoleate the most important auxiliary is an ethoxylated cetylstearyl alcohol.



# **REGISTER OF CHEMICAL**/ **MONOGRAPH NAMES**

CHEMICAL/MONOGRAPH NAME	PRODUCT	PAGE
В		
Bis-diglyceryl polyacyladipate-2	SOFTISAN® 649	11
Butylene glycol dicaprylate/dicaprate	MIGLYOL <sup>®</sup> 8810	9
С		
Caprylic/capric/succinic triglyceride	MIGLYOL <sup>®</sup> 829	9
Cocoyl Caprylocaprate NON-GMP	MIGLYOL® 128	9
G		
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)	SOFTISAN® 601	11
Glycerol monocaprylate, type l	IMWITOR® 988	7
Glycerol monocaprylate, type II NON GMP	IMWITOR® 308	6
Glycerol monocaprylocaprate, type I	IMWITOR® 742	7
Glycerol mono-oleate	IMWITOR® 948	7
Glycerol monostearate 40–55%, type l	IMWITOR <sup>®</sup> 900 (F)	7
Glycerol monostearate 40–55%, type II	IMWITOR <sup>®</sup> 900 K	7
Glyceryl citrate/lactate/linoleate/oleate	IMWITOR® 375	6
Glyceryl monostearate	IMWITOR® 491	6
Glyceryl monostearate, self-emulsifying	IMWITOR <sup>®</sup> 960 K	7
Glyceryl stearate citrate	IMWITOR® 372 P	6
Glyceryl tristearate	DYNASAN® 118	5

CHEMICAL	MONOGRAPH	NAME
UTLINIOAL/		

#### Н

Hard fat, Adeps solidus

#### Hard fat + beeswax

Hard fat + polyoxyethylene (25) cetyl/stearyl ether + Beeswax

Hard Fat + Polyoxyethylene (25) Cetyl Stearyl Ether + glyceryl ricinoleate (stabilized)

Hard fat + glyceryl ricinoleate (stabilized)

Hydrogenated palm oil

#### Μ

Macrogol-6 glycerol caprylocaprate

Medium-chain triglyceride

#### Ρ

Polyglyceryl-3 polyricinoleate

Propylene glycol dicaprylocaprate

Т Trimyristin Tripalmitin

PRODUCT	PAGE
WITEPSOL® H 5, H 12, H 15, H 32, H 35, H37	7 13
WITEPSOL® W 25, W 32, W 35, W 45	14
WITEPSOL® E 76, E 85	14
SOFTISAN® 378	11
WITEPSOL® E 75	14
WITEPSOL® S 55	15
WITEPSOL® S 58, S 51	15
WITEPSOL® H 19	13
SOFTISAN® 154	11
SOFTIGEN® 767	10
MIGLYOL® 810 N, 812 N Drug Substance, 812 N Excipient	9
IMWITOR <sup>®</sup> 600	6
MIGLYOL <sup>®</sup> 840	9
DYNASAN® 114	5
DYNASAN® 116	5

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