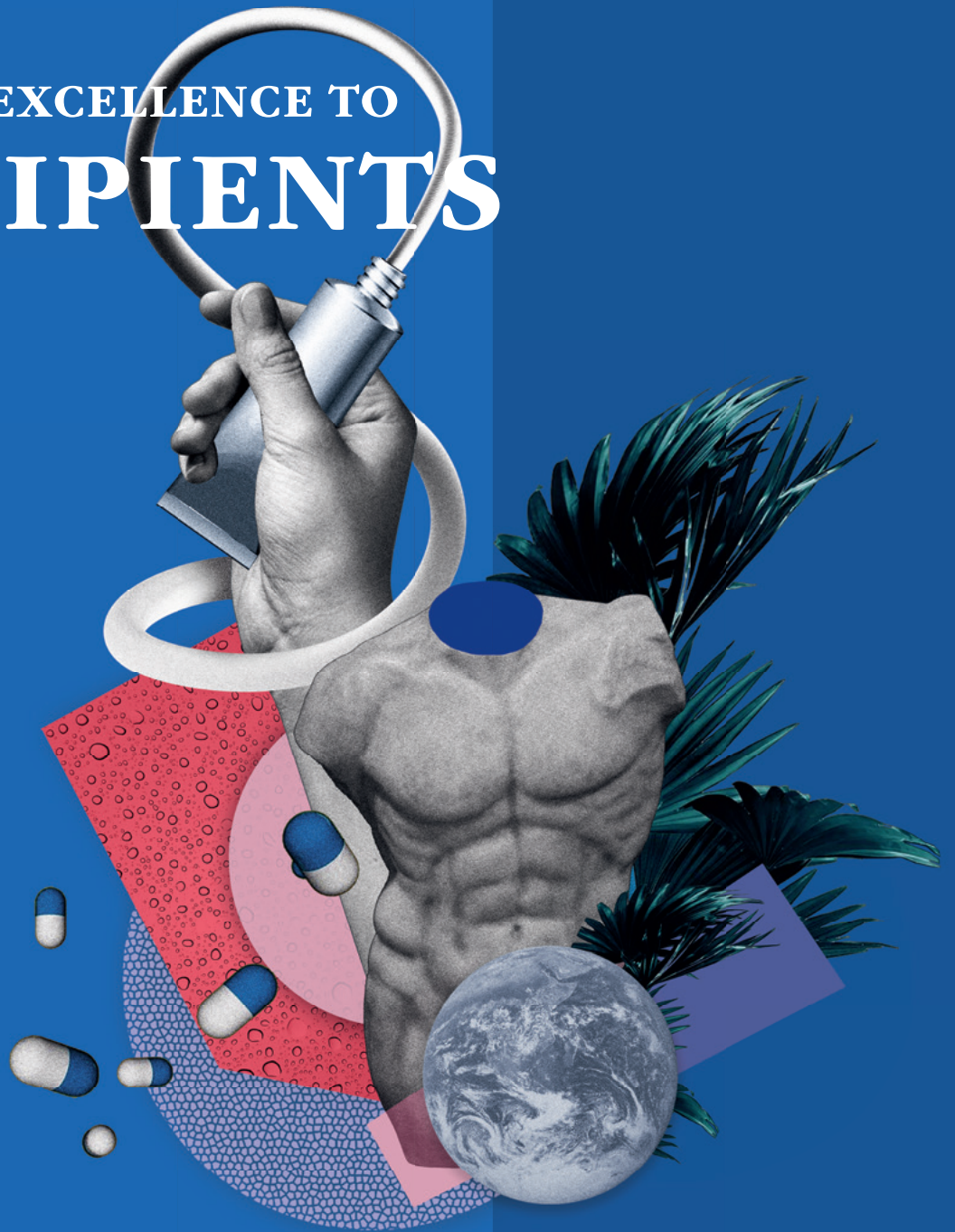




IOI OLEOCHEMICAL

PHARMA

WE ADD EXCELLENCE TO  
**EXCIPIENTS**



IOI Oleo GmbH



## Tried & Trusted – 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®** Purified monoacid triglycerides
- ✓ **IMWITOR®** Highly functionalized lipids for drug delivery systems
- ✓ **MIGLYOL®** Reference-quality C8-C 10 esters for pharma formulations
- ✓ **SOFTIGEN®** Compendial liquid solubilizer
- ✓ **SOFTISAN®** Specialties for topical and oral applications
- ✓ **WITEPSOL®** Benchmark hard fats for suppositories and ovules

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

### Abbreviations:

CEP = Certificate of Suitability of 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 Pharmacopoeia-National Formulary

BP = British Pharmacopoeia

FCC = Food Chemicals Codex

HLB = Hydrophilic-lipophilic balance

GRAS = Generally Recognized As Safe

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

# DYNASAN®

Purified monoacid triglycerides



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

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**Product name:** DYNASAN® 114

**Chemical description/monograph name:**

Trimyristin

**Melting point °C:** 55-60

**Hydroxyl value mg KOH/g:** max. 10

**Properties and applications:**

Drug Carrier  
Consistency Regulator  
Taste masking  
Hot Melt Coating  
Tablet Lubricant

A high melting point lipid for use in modified/sustained release in oral solid dosage matrices and effective lubricant for tablets/capsules.

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**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.

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**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:**

Drug Carrier  
Consistency Regulator  
Taste masking  
Hot Melt Coating  
Tablet Lubricant

Effective non-ionic substitute for metal soaps of fatty acids in tablet production in low concentrations (~ 0.5%).  
No influence on drug release up to a concentration of 1%.  
From 2 to 5% hydrophobic characteristics of the tablet matrix increase and introduce sustained release characteristics.  
Enhances the tablet fracture stability.

# IMWITOR®

## Highly 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:**

Drug Carrier

Solubilizer

Bioavailability Booster

Co-Emulsifier O/W

Refatting Agent

Excellent antibacterial properties. Up to 10% of water can be dissolved to obtain a clear solution.

**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.

**Recommended Concentration:** 2 - 4% as main emulsifier, 0.5 - 2.0% as co-emulsifier

**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. Cold processable

**Recommended Concentration:** 1-3% as main emulsifier, 0.5 - 2% as co-emulsifier or solubilizer in anhydrous systems

**Product name:** [IMWITOR® 491](#)

**Chemical description/monograph name:**

Glyceryl Monostearate

**Listed in:** USP-NF

**Additional quality information:** NON-GMP

**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. Excellent stability even with high water content.

**Recommended Concentration:** 2 to 4%

**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:**

Drug carrier and solubilizer for poorly water-soluble drugs that fall into class II and IV of the Biopharmaceutical Classification System (BCS).

Co-Emulsifier

Defoamer

Water-Soluble up to 10%

**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 (e.g. granulation, hot melt technique).

O/W emulsifier

Emulsion Stabilizer

Tablet lubricant

Dispersing agent for sustained release

**Recommended Concentration:** 1-3%

**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 (e.g. granulation, hot melt technique).

O/W emulsifier

Emulsion Stabilizer

Tablet lubricant

Dispersing agent for sustained release

**Product name:** [IMWITOR® 948](#)

**Chemical description/monograph name:**

Glycerol Mono-Oleate 40

**Listed in:** Ph. Eur., USP-NF

**Appearance:** Yellowish, liquid to pasty

**Content of monoglycerides:** 32-52%

**Properties and applications:** O/W stabilizer and Co-Emulsifier, forms gels in excess water. Contains an antioxidant.

**Recommended Concentration:** 1 to 3%

**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. Emulsion stabilizer for rich creams and ointments.

**Recommended Concentration:** 2 to 7%

**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®

Reference-quality C8-C 10 esters for pharma formulations



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.

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**Product name:** MIGLYOL® 128

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**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:** Low viscosity, fast spreading non-polar emollient and refatting agent. Vegetable alternative for light petrochemical emollients or silicones (e.g. D5)

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**Product name:** MIGLYOL® 810 N

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**Chemical description/monograph name:**

Triglyceride, medium-chain / MCT neutral oil (C8/C10 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.

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

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**Chemical description/monograph name:**

Triglyceride, medium-chain / MCT neutral oil (C8/C10 ratio ~ 60:40%)

**Listed in:** Ph. Eur., USP-NF, JPE, valid CEP, 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.

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

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**Chemical description/monograph name:**

Triglyceride, medium-chain / MCT neutral oil (C8/C10 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. Excellent stability against thermal and oxidative stress

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**Product name:** MIGLYOL® 829

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**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.

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**Product name:** MIGLYOL® 840

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**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:** A polar, high spreading emollient with low viscosity. Excellent dispersing and solvent properties, favoured for i.m. injectables and pour-on formulations. Very high stability against thermal and oxidative stress. Low impurity profile for improved drug quality.

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**Product name:** MIGLYOL® 8810

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**Chemical description/monograph name:**

Butylene Glycol Dicaprylate/Dicaprate

**Additional quality information:** NON-GMP

**Appearance:** Colorless oil of low viscosity

**Viscosity mPa·s 20 °C:** ~ 13.0

**Properties and applications:** Completely saturated, non-oxidizing 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.

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# SOFTIGEN®

Compendial liquid solubilizer

# SOFTISAN®

Specialties for topical and oral applications

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

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**Product name:** SOFTIGEN® 767

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**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). Forms micelles from >0,5% of usage concentration and enables clear formulations.

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**Product name:** SOFTISAN® 154

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**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. Lipophilic matrix for SLN for controlled drug release, similar to hydrogenated vegetable oil.

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**Product name:** SOFTISAN® 378

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**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. Excellent stability against thermal and oxidative stress. Odorless and neutral taste. Can be used e.g. as emollient in topical formulations or capsule filling mass.

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**Product name:** SOFTISAN® 601

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**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, e.g. Ketoprofen, Paracetamol, Heparine, Miconazol.

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**Product name:** SOFTISAN® 649

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**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®

Benchmark 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

**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

**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

**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 + Glycerol 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

**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

**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

**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®

Benchmark hard fats for suppositories and ovules

**Product name:** WITEPSOL® W 25

**Chemical description/monograph name:**

Hard Fat, Adeps solidus

**Listed in:** Ph. Eur., USP-NF, JPE

**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

**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

**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

**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

**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

**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

**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 + Glycerol Ricinoleate (stabilized)

**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

**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 + Glycerol Ricinoleate (stabilized)

**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 glycerol ricinoleate the most important auxiliary is an ethoxylated cetylstearyl alcohol.





# REGISTER OF CHEMICAL/ MONOGRAPH NAMES

CHEMICAL/MONOGRAPH NAME	PRODUCT	PAGE
<b>B</b>		
Bis-Diglyceryl Polyacyladipate-2	SOFTISAN® 649	11
Butylene Glycol Dicaprylate/Dicaprate	MIGLYOL® 8810	9
<b>C</b>		
Caprylic/Capric/Succinic Triglyceride	MIGLYOL® 829	9
Cocoyl Caprylocaprate	MIGLYOL® 128	9
<b>G</b>		
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 I	IMWITOR® 988	7
Glycerol Monocaprylate, Type II	IMWITOR® 308	6
Glycerol Monocaprylocaprate, Type I	IMWITOR® 742	7
Glycerol Mono-Oleate	IMWITOR® 948	7
Glycerol Monostearate 40-55%, Type I	IMWITOR® 900 (F)	7
Glycerol Monostearate 40-55%, Type II	IMWITOR® 900 K	7
Glyceryl Citrate/Lactate/Linoleate/Oleate	IMWITOR® 375	6
Glyceryl Monostearate	IMWITOR® 491	6
Glyceryl Monostearate, self-emulsifying	IMWITOR® 960 K	7
Glyceryl Stearate Citrate	IMWITOR® 372 P	6
Glyceryl Tristearate	DYNASAN® 118	5

CHEMICAL/MONOGRAPH NAME	PRODUCT	PAGE
<b>H</b>		
Hard Fat, Adeps solidus	WITEPSOL® H 5, H 12, H 15, H 32, H 35, H37	13
	WITEPSOL® W 25, W 32, W 35, W 45	14
	WITEPSOL® E 76, E 85	14
	SOFTISAN® 378	11
Hard Fat + Beeswax	WITEPSOL® E 75	14
Hard Fat + Polyoxyethylene (25) Cetyl/Stearyl Ether + Beeswax	WITEPSOL® S 55	15
Hard Fat + Polyoxyethylene (25) Cetyl Stearyl Ether + Glyceryl Ricinoleate (stabilized)	WITEPSOL® S 58, S 51	15
Hard Fat + Glyceryl Ricinoleate (stabilized)	WITEPSOL® H 19	13
Hydrogenated Palm Oil	SOFTISAN® 154	11
<b>M</b>		
Macrogol-6 Glycerol Caprylocaprate	SOFTIGEN® 767	10
Medium-Chain Triglyceride	MIGLYOL® 810 N, 812 N Drug Substance, 812 N Excipient	9
<b>P</b>		
Polyglyceryl-3 Polyricinoleate	IMWITOR® 600	6
Propylene Glycol Dicaprylocaprate	MIGLYOL® 840	9
<b>T</b>		
Trimyristin	DYNASAN® 114	5
Tripalmitin	DYNASAN® 116	5



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

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