



# IOI OLEOCHEMICAL

**IOI Oleo GmbH  
PHARMA**

## Technical Data Sheet | WITEPSOL®

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**Ph. Eur. name: Hard Fat, Adeps Solidus**

**USP name: Hard Fat**

### 1. Description

Hard fat bases for production of suppositories and ovules.

### 2. Properties

They are white or almost white, odourless hard fats in pastill shape and comprise of glycerides of plant origin. Some hard fats contain certain additives and do therefore not comply with the monograph.

### 3. Applications

WITEPSOL hard fat bases are used for manufacturing suppositories and ovules.

Due to the fact that hard fats containing no additives are GRAS listed, WITEPSOL bases containing no additives can be used in the following applications:

- capsule fillings
- chewing tablets
- SLN (Solid Lipid Nanoparticles) processes
- microencapsulation
- implants



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### 4. Chemical and Physical Properties

	Slip melting point [°C] Ph. Eur. 2.2.15	Acid value [mg KOH/g] Ph. Eur. 2.5.1	Hydroxyl value [mg KOH/g] Ph. Eur. 2.5.3	Peroxide value [meq O/kg] Ph. Eur. 2.5.5	Saponification value [mg KOH/g] Ph. Eur. 2.5.6
WITEPSOL H 5	34.0 – 36.0 [34.9]	max. 0.5 [0.1]	max. 5 [2]	max. 3.0 [0.3]	235 – 245 [241]
WITEPSOL H 12	32.0 – 33.5 [32.8]	max. 0.5 [0.1]	5 – 15 [11]	max. 3.0 [0.2]	240 – 255 [243]
WITEPSOL H 15	33.5 – 35.5 [34.7]	max. 0.5 [0.1]	5 – 15 [13]	max. 3.0 [0.3]	230 – 245 [239]
<b>WITEPSOL H 19*</b>	<b>33.5 – 35.5 [34.8]</b>	<b>max. 5 [0.2]</b>	<b>20 – 30 [27]</b>	<b>max. 15 [0.2]</b>	<b>230 – 240 [235]</b>
WITEPSOL H 32	31.0 – 33.0 [31.9]	max. 0.5 [0.1]	max. 3 [2]	max. 3.0 [0.2]	240 – 250 [248]
WITEPSOL H 35	33.5 – 35.5 [34.5]	max. 0.5 [0.1]	max. 3 [1.5]	max. 3.0 [0.2]	240 – 250 [245]
WITEPSOL H 37	36.0 – 38.0 [36.7]	max. 0.5 [0.1]	max. 3 [1.9]	max. 3.0 [0.1]	225 – 245 [237]
WITEPSOL W 25	33.5 – 35.5 [34.2]	max. 0.5 [0.1]	20 – 30 [25]	max. 3.0 [0.5]	225 – 240 [234]
WITEPSOL W 32	32.0 – 33.5 [32.8]	max. 0.5 [0.2]	40 – 50 [45]	max. 3.0 [0.4]	225 – 245 [232]
WITEPSOL W 35	33.5 – 35.5 [34.4]	max. 0.5 [0.2]	40 – 50 [45]	max. 3.0 [0.6]	225 – 235 [230]
WITEPSOL W 45	33.5 – 35.5 [34.3]	max. 0.5 [0.2]	40 – 50 [47]	max. 3.0 [0.3]	225 – 240 [233]
<b>WITEPSOL S 51*</b>	<b>30.0 – 32.0 [31.1]</b>	<b>max. 5 [0.3]</b>	<b>55 – 70 [61]</b>	<b>max. 15 [0.5]</b>	<b>215 – 230 [225]</b>
<b>WITEPSOL S 55*</b>	<b>ca. 35**</b>	<b>max. 5 [0.8]</b>	<b>50 – 65 [56]</b>	<b>max. 15 [1]</b>	<b>215 – 230 [223]</b>
<b>WITEPSOL S 58*</b>	<b>31.5 – 33.0 [32.2]</b>	<b>max. 5 [0.3]</b>	<b>60 – 70 [66]</b>	<b>max. 15 [0.7]</b>	<b>215 – 225 [222]</b>
<b>WITEPSOL E 75*</b>	<b>ca. 38**</b>	<b>max. 2 [1.0]</b>	<b>max. 15 [12]</b>	<b>max. 3.0 [0.4]</b>	<b>220 – 230 [226]</b>
WITEPSOL E 76	37.0 – 39.0 [38.0]	max. 0.5 [0.2]	30 – 40 [35]	max. 3.0 [0.3]	220 – 230 [228]
WITEPSOL E 85	42.0 – 44.0 [43.2]	max. 0.5 [0.1]	5 – 15 [13]	max. 3.0 [0.2]	220 – 240 [223]
<b>Monograph requirements</b>					
Ph. Eur.	30 - 45	max. 0.5	max. 50	max. 3.0	210 – 260
USP	27 - 44	max. 1.0	max. 70	-	215 – 255
JPE	30 - 45	max. 2.0	max. 70	-	210 – 255

**Highlighted** hard fat bases contain certain additives: H 19: Glyceryl Ricinoleate (stabilized), E 75: Bees Wax, S 51: Macrogol Cetostearyl ether + Glyceryl Ricinoleate (stabilized), S 55: Macrogol Cetostearyl ether + Bees Wax, S 58: Macrogol Cetostearyl ether + Glyceryl Ricinoleate (stabilized).

**These hard fats do not comply with the monographs “Hard Fat With Additives” of Ph. Eur. or with the monograph “Hard Fat” of USP.**



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### 5. Additional Information

\* WITEPSOL grades **H 19, S 51, S 55, S 58 and E 75** are mixtures of hard fats (Ph. Eur.) with additives.

**These mixtures do not comply with the monograph “Hard Fat with Additives” of Ph. Eur. or with the monograph “Hard Fat” of USP-NF.**

\*\* Due to the additive bees wax, the slip melting points are hard to reproduce (adhesion at the inner surface of the glass capillary). The solidification points can be determined more precisely.

Solidification point WITEPSOL E 75: 34 – 36.5 °C [36.0]

Solidification point WITEPSOL S 55: 28 – 33°C [29.5]

**Values in brackets [ ] are nominal values.**

We confirm that all other tests requirements, indicated in the monograph, will be fulfilled.

#### **Solubility**

WITEPSOL hard fats are readily soluble in diethylether, toluene and n-hexane and slightly soluble in anhydrous ethanol and methylene chloride. They are practically insoluble in water.

The WITEPSOLs have been assigned the type IV US DMF no. 420.

### 6. Packaging Information

Pastilles in carton boxes with a PE inliner of 20 kg net, except Witepsol types H 32 and H 35 which are delivered in carton boxes with 15 kg net.

### 7. Storage and Shelf Life

Longterm storage in original tightly closed containers, dry, protected from light and moisture and below 25°C the shelf life then is at least three years.

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