



IOI OLEOCHEMICAL

PHARMA

SOFTISAN[®] 378

TECHNICAL DATA SHEET

Ph. Eur. (current version):
USP (current version):

Hard Fat
Hard Fat

DESCRIPTION

SOFTISAN® 378 is a specialty blend of triglycerides based on C₈ - C₁₈ fatty acids and glycerol. Fatty acids and glycerol are based on vegetable sources. It is free from antioxidants and other stabilizing additives.

APPLICATION

SOFTISAN® 378 is used as a non-oxidizing fat base in the pharmaceutical industry. It is particularly suitable for processing in high-quality dermal preparations because the skin is provided with a similar triglyceride mixture that is not tacky and, unlike paraffins, does not leave a greasy shine.

SOFTISAN® 378 allows for rapid melting of the product on the skin, and incorporated active ingredients are therefore quickly released. In addition SOFTISAN® 378 has absorption-promoting properties and behaves in a neutral manner towards active substances.

SOFTISAN® 378 is also suitable as a carrier of active ingredients in hard and soft gelatine capsules.

SOFTISAN® 378 can be easily incorporated, either in molten or cold state, in ointments, creams, lotions and pastes. Owing to its purely vegetable origin and its mode of production, SOFTISAN® 378 is free of any skin-irritating substances such as toxic heavy metals, catalysts, solvents, antioxidants and other stabilizers.

SOFTISAN® 378 is a white to ivory-coloured solid mass with a consistency similar to pork lard. It is characterized by a neutral fatty odour and a mild fatty taste. It provides a superior oxidation stability and product uniformity. Therefore SOFTISAN® 378 exhibits a long shelf life without a risk of rancidity.



CHEMICAL AND PHYSICAL PROPERTIES

Tests	Values	Typical values	Units	Methods
Acid value	max. 0.5	0.2	mg KOH/g	Ph. Eur. 2.5.1
Saponification value	245 – 260	253	mg KOH/g	Ph. Eur. 2.5.6
Hydroxyl value	max. 50	12	mg KOH/g	Ph. Eur. 2.5.3
Drop point #	39 – 42	39.3	°C	Ph. Eur. 2.2.17

SOFTISAN 378 fully complies with the requirements of the current Ph. Eur. monograph “Hard Fat”.

Above mentioned tests are a selection of relevant parameters and do not represent the complete current sales specification.

= Slip melting point determination is difficult to reproduce (37 – 40°C), because of its fatty acid distribution (due to adhesion to the glass capillary). The drop point method is more precise.

Solubility

SOFTISAN® 378 is readily soluble in diethylether, toluene and n-hexane; soluble in acetone and ethanol when heated. It is insoluble in water and miscible with fats and oils. SOFTISAN® 378 has excellent skin compatibility and it is harmless, even when ingested orally (edible fat). It spreads well on the skin and penetrates easily. It does not inhibit natural skin respiration and has an absorption-promoting effect.



ADDITIONAL INFORMATION

The fatty acids used for the production of SOFTISAN 378 complies with CFR 21, § 172.860.

SOFTISAN 378 exhibits a fractionated glycerides crystallization. So, if only small amounts shall be removed from the container, it is highly recommended to always heat the complete container to approx. 60°C for an appropriate time (until completely molten) in order to obtain a completely liquid phase without any lumps or residues of unmolten fat. Stir well in order to get a fully homogeneous phase prior to pulling an aliquote sample.

PACKAGING UNITS

Solid mass in HDPE containers of 25 kg net, steel drums with an inner lacquer lining of 180 kg net.

HANDLING AND SHELF LIFE

If stored longterm 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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