METAPHARMACEUTICAL IND SL
Josep Plà, 163, 2n 5a / Tel. 933 089 976 / info@metapharmaceutical.com

TECHNICAL DATA SHEET

003718-TDS-ENG-2025

SORBITAN SESQUIOLATO (EUR. PH.)		
DESCRIPTION DCI: ---	DESCRIPTION DOE: ---	
CAS Nº: 8007-43-0	EC Nº: 232-360-1	AEMPS CODE: ---
MOL. WEIGHT: ---	MOL. FORMULA: ---	ARTICLE CODE: 003718

ATTRIBUTES	SHOULD BE
Appearance	Pale yellow or slightly brownish-yellow paste, which becomes a viscous, oily, brownish-yellow liquid at about 25 ºC
Solubility	Dispersible in water, soluble in fatty oils, slightly soluble in ethanol (96 %)
Relative density	about 0.99 g/mL
Identification A	Complies
Identification B	Complies
Identification C	Complies
Acidity index	=< 16.0
Hydroxyl value	180 - 215
Iodine index	70 - 95
Peroxide value	=< 10.0
Saponification index	145 - 166
Fatty acids composition	
Myristic acid	=< 5.0 %
Palmitic acid	=< 16.0 %
Palmitoleic acid	=< 8.0 %
Stearic acid	=< 6.0 %
Oleic acid	65.0 - 88.0 %
Linoleic acid	=< 18.0 %
Linolenic acid	=< 4.0 %
Fatty acids > C18	=< 4.0 %
Margaric acid	=< 0.2 %
Water	=< 1.5 %
Total ash	=< 0.5 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Store in original container. Keep the container tightly closed in a dry and well-ventilated place.

REMARKS

This product has been manufactured and tested to GMP in accordance with EXCiPACT.

Sorbitan Sesquioletae is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

TECHNICAL DATA SHEET

003718-TDS-ENG-2025

SORBITAN SESQUIOLATO (EUR. PH.)		
DESCRIPTION DCI: ---	DESCRIPTION DOE: ---	
CAS Nº: 8007-43-0	EC Nº: 232-360-1	AEMPS CODE: ---
MOL. WEIGHT: ---	MOL. FORMULA: ---	ARTICLE CODE: 003718

The product is from vegetal origin and no animal product is used in its production, so it is risk-free BSE/TSE.

The product is not derived from GMO. No genetically modified organism is used in its production and no GMO product comes in contact with the product during any stage of production.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.