

## SORBITAN SESQUIOLATO (EUR. PH.)

PRODUCT CODE: 003718	CAS Nº: 8007-43-0	ANALYSIS Nº: 136/24
MANUFACTURER BATCH: 0002303282	CERTIFICATE ID: 42.237	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 29/04/2024	
METAPH BATCH: 0210524	RETEST DATE: 29/04/2026	

ATTRIBUTES	SHOULD BE	IS
Appearance	Pale yellow or slightly brownish-yellow paste, which becomes a viscous, oily, brownish-yellow liquid at about 25 °C	Slightly brownish-yellow paste, which becomes a viscous, oily, brownish-yellow liquid at about 25 °C
Relative density	about 0.99 g/mL	0.99 g/mL
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification C	Complies	Complies
Acidity index	=< 16.0	7 mg KOH/g (*)
Hydroxyl value	180 - 215	195 mg KOH/g
Iodine index	70 - 95	85 g I2/100g
Peroxide value	=< 10.0	0 meq/Kg (*)
Saponification index	145 - 166	159 mg KOH/g (*)
Fatty acids composition		
Myristic acid	=< 5.0 %	< 0.1 %
Palmitic acid	=< 16.0 %	4.7 %
Palmitoleic acid	=< 8.0 %	1.5 %
Stearic acid	=< 6.0 %	1.4 %
Oleic acid	65.0 - 88.0 %	77.5 %
Linoleic acid	=< 18.0 %	14.0 %
Linolenic acid	=< 4.0 %	0.8 %
Fatty acids > C18	=< 4.0 %	0.2 %
Margaric acid	=< 0.2 %	< 0.1 %
Water	=< 1.5 %	0.2 % (*)
Total ash	=< 0.5 %	< 0.5 % (*)

### COMPLIES WITH

European Pharmacopoeia 11.0

### REMARKS

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

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

(\*) Data adapted from the manufacturer's certificate of analysis.

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.

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,

Analysis date: 03/06/2024  
 Signature: Albert Sanchez Lopez (QP)  
 Conclusion: Complies

Manufacturer: 40000217





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which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

### STORAGE

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

Analysis date: 03/06/2024  
Signature: Albert Sanchez Lopez (QP)  
Conclusion: Complies

Manufacturer: 40000217