

SPEZIOL[®] MD PHARMA

Further Product Name

Ph. Eur.: "Glycerol monostearate 40-55 (typ I)"

BP: "Glycerol monostearate 40-55 (typ I)"

General Characterization

On account of its consistency giving characteristics it is mainly used for the viscosity adjustment in pharmaceutical O/W emulsions.

Chemical description

Glyceryl monostearate

Characteristic Values

The specifications stated below finally and conclusively describe the properties of the product.

Quality control data

Data which is used for quality release and is specified for each batch.

	corresponds to the standard	
	corresponds to the standard	
	54 - 64 °C	
Identification A	conforms	Ph. Eur. 2.2.15
Identification B	conforms	Ph. Eur. 2.2.27
Identification C	conforms	Ph. Eur. 2.4.22 method C
Identification D	conforms	Ph. Eur. 0495
Acid value	max 3.0	Ph. Eur. 2.5.1
Iodine value	max 3.0	Ph. Eur. 2.5.4
Saponification value	158 - 177	Ph. Eur. 2.5.6
Free glycerol	max 6.0 %	Ph. Eur. 0495
Composition of fatty acids		
Stearic acid	40.0 - 60.0 %	Ph. Eur. 2.4.22 method C
Sum Palmitic and Stearic acid	min 90.0 %	Ph. Eur. 2.4.22 method C
Nickel	max 1 ppm	Ph. Eur. 2.4.27
Water	max 1.0 %	Ph. Eur. 2.5.12
Total ash	max 0.1 %	Ph. Eur. 2.4.16
Assay		
Monoacylglycerol	40.0 - 55.0 %	Ph. Eur. 0495
Diacylglycerol	30.0 - 45.0 %	Ph. Eur. 0495
Triacylglycerol	5.0 - 15.0 %	Ph. Eur. 0495

Methods of identification

As described in the current Monograph of the Ph. Eur.

Methods of analysis

All test and assay methods are as described in the current Monograph of the Ph. Eur.

Storage, Packaging and Shelflife

Storage Conditions

In sealed original containers, protected from moisture and at temperatures below 30° C, SPEZIOL® MD PHARMA remains stable for at least one year.

Labeling Information & Registrations

INCI name(s)

Glyceryl Stearate

Officially listed in / Quality conforms to

Ph. Eur.	Conforms to the current analytical specification in the monograph "Glycerol monostearate 40-55 (typ I)"
BP	Conforms to the current analytical specification in the monograph "Glycerol monostearate 40-55 (typ I)" (copy of the Ph. Eur. monograph)
JCIC	Glyceryl Monostearate, Lipophilic (Ingredient Code 102544)
CAS-No.	67701-33-1
EINECS-No.	266-952-6
Residual solvents	Conforms to current ICH Guideline (CPMP/ICH/283/95) & Residual Solvents <467>
Minimising animal spongiform encephalopathy agents	Conforms to requirements Ph. Eur. 5.2.8

Disclaimer

All products in the text marked with an ® are trademarks of the Cognis group. The information on product specifications provided herein is only binding to the extent confirmed by Cognis in a written Sales Agreement. COGNIS EXPRESSLY DISCLAIMS ANY RESPONSIBILITY FOR THE SUITABILITY OF THE PRODUCTS FOR ANY SPECIFIC OR PARTICULAR PURPOSES INTENDED BY THE USER. Suggestions for the use and application of the products and guide formulations are given for information purposes only and without commitment. Such suggestions do not release Cognis' customers from testing the products as to their suitability for the customer's intended processes and purposes. Cognis does not assume any liability or risk involved in the use of its products as the conditions of use are beyond its control. The user of the products is solely responsible for compliance with all laws and regulations applying to the use of the products, including intellectual property rights of third parties.