

MYRITOL[®] 318 PH**Further Product Name**

Ph. Eur.: "Triglycerides medium-chain"

BP: "Triglycerides medium-chain" (copy of the Ph. Eur. monograph)

NF: "Medium-Chain Triglycerides"

General Characterization

MYRITOL[®] 318 PH is a clear, slightly yellowish, polar, odourless oil with a mean molecular weight. Due to its mean spreading value, the product can be universally applied in pharmaceutical skin care preparations and well-fattening emulsions and skin oils.

Chemical description

Triglycerid on base of saturated fatty acids C8 and C10

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.

Appearance	conforms	Ph. Eur. 2.2.2 method I
Dilution appearance	conforms	Ph. Eur. 2.2.1
Acid value	max 0.2	Ph. Eur. 2.5.1
Hydroxyl value	max 10	Ph. Eur. 2.5.3 method A
Iodine value	max 1.0	Ph. Eur. 2.5.4
Peroxide value	max 1.0	Ph. Eur. 2.5.5 method A
Saponification value	310 - 360	Ph. Eur. 2.5.6
Relative density	0.93 - 0.96 g/mL	Ph. Eur. 2.2.5
Refractive index	1.440 - 1.452	Ph. Eur. 2.2.6
Viscosity	25 - 33 mPa*s	Ph. Eur. 2.2.9
Water	max 0.1 %	Ph. Eur. 2.5.12
Unsaponifiable matter	max 0.5 %	Ph. Eur. 2.5.7
Ash	max 0.1 %	Ph. Eur. 2.4.16
Alkaline impurities	max 0.15 mL	Ph. Eur. 0868
Caproic acid	max 2.0 %	Ph. Eur. 2.4.22 method C
Caprylic acid	50.0 - 80.0 %	Ph. Eur. 2.4.22 method C
Capric acid	20.0 - 50.0 %	Ph. Eur. 2.4.22 method C
Lauric acid	max 3.0 %	Ph. Eur. 2.4.22 method C
Myristic acid	max 1.0 %	Ph. Eur. 2.4.22 method C
Caprylic and Capric acid	min 95.0 %	Ph. Eur. 2.4.22 method C
Heavy metals	max 10 ppm	Ph. Eur. 2.4.8 method D
Appearance	conforms	USP/NF <631>
Identification A	conforms	USP/NF
Identification B	conforms	USP/NF
Density (20°C)	0.93 - 0.96 g/mL	USP/NF <841>
Acid value	max 0.2	USP/NF <401>
Hydroxyl value	max 10	USP/NF <401>
Iodine value	max 1.0	USP/NF <401>
Peroxide value	max 1.0	USP/NF <401>
Saponification value	310 - 360	USP/NF <401>
Unsaponifiable matter	max 0.5 %	USP/NF <401>
Caproic acid	max 2.0 %	USP/NF <401>
Caprylic acid	50.0 - 80.0 %	USP/NF <401>
Capric acid	20.0 - 50.0 %	USP/NF <401>
Lauric acid	max 3.0 %	USP/NF <401>
Myristic acid	max 1.0 %	USP/NF <401>
Caprylic and Capric acid	min 95.0 %	USP/NF <401>
Viscosity	25 - 33 mPa*s	USP/NF <911>
Refractive index (20°C)	1.440 - 1.452	USP/NF <831>
Alkaline impurities	max 0.15 mL	USP/NF
Water	max 0.1 %	USP/NF <921> method I
Total ash	max 0.1 %	USP/NF <561>
Heavy metals	max 10 ppm	USP/NF <231> method II
Pesticides residue	conforms	Ph. Eur. 2.8.13 table 1
Microbiological status	conforms	Ph. Eur. 5.1.4 category 2 & 3a

Rev. 1.0

Aflatoxines
Heavy metals

conforms
conforms

Federal Health Gazette Ban V 2000
Federal Health Gazette 1985

Methods of identification

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

Methods of analysis

All test and assay methods are as described in the current Monograph of the Ph. Eur. or NF if not otherwise mentioned.

Storage, Packaging and Shelflife

Storage Conditions

In the original sealed containers MYRITOL® 318 PH can be stored for at least one year, protected from moisture at below 30°C.

Labeling Information & Registrations

INCI name(s)

Caprylic/Capric Triglyceride

Officially listed in / Quality conforms to

Ph. Eur.	Conforms to the current analytical specification in the monograph "Triglycerides medium-chain"
BP	Conforms to the current analytical specification in the monograph "Triglycerides medium-chain" (copy of the Ph. Eur. Monograph)
NF	Conforms to the current analytical specification in the monograph "Medium-chain Triglycerides"
US DMF no. (Typ IV)	#16495
JCIC	Caprylic/Capric Acid Triglyceride (Ingredient Code 111164)
CAS-No.	73398-61-5
EINECS-No.	277-452-2
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

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Rev. 1.0