

TECHNICAL DATA SHEET

- PLUROL DIISOSTEARIQUE -

DEFINITION

Triglycerol diisostearate EP / Polyglyceryl-3 diisostearate NF.

ORIGIN OF THE RAW MATERIALS

The product is manufactured from raw materials of strictly vegetable origin.

DESCRIPTION

- INCI (PCPC): Polyglyceryl-3 Diisostearate
- CAS: 63705-03-3
- EINECS: Not applicable

REGULATORY INFORMATION

- Pharmacopeia conformity: Product conforms to EP, USP/NF.
- For information on the regulatory status of this product, please consult the regulatory data sheet (RDS).

FIELD OF USE

This product is a pharmaceutical ingredient. It is recommended for use in pharmaceutical formulations administered by topical and/or rectal/vaginal routes.

This ingredient must be used according to appropriate regulations. Gattefossé accepts no responsibility for the use of this product in applications other than those recommended.

USES

Dermal drug delivery: Non-ionic W/O emulsifier.

STORAGE RECOMMENDATIONS

Store the product in its original packaging sealed tightly, protected from light and moisture.

Special temperature storage conditions are not required.

Container packaged under nitrogen.

A partial crystallization of the product may occur during storage at low temperature with no effect on the properties of the product. It disappears after heating and homogenization.

Product should be re-analyzed after a 3-year storage period under recommended storage conditions.

HANDLING ADVICE

Presentation: liquid.

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HANDLING ADVICE

In case of crystallization, heat at 40-50 °C and homogenize before use.

Container packaged under nitrogen. Flush with nitrogen after each opening of the container or use it rapidly.

For additional information, please consult the product handling sheet.

PACKAGING

Steel drum 25 kg (BFC).

Sample available upon request.

SAFETY OF USE

For information on the toxicology and safety of this product, please consult the product tox and safety overview.

SOLUBILITIES AT 20°C(Eur. Ph.)

- Ethanol 96°: Soluble
- Chloroform, Methylene chloride: Soluble
- Water: Insoluble
- Vegetable oils: Soluble
- Mineral oils: Soluble

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Test	Specification
APPEARANCE	Viscous liquid
ODOUR	Faint
COLOUR (Gardner Scale)	<= 5.0
REFRACTIVE INDEX AT 20°C	1.469 to 1.475
ACID VALUE	<= 3.00 mgKOH/g
SAPONIFICATION VALUE	128 to 160 mgKOH/g
IODINE VALUE	<= 3.0 gI ₂ /100g
HYDROXYL VALUE	180 to 230 mgKOH/g
PEROXIDE VALUE	<= 6.0 meqO ₂ /kg
WATER CONTENT	<= 0.50 %
HEAVY METALS CONTENT (Pb)	< 10 ppm
RESIDUE ON IGNITION	<= 0.50 %
SUM OF FATTY ACIDS ELUTING C16 to C18	>= 60.0 %
SUM OF FATTY ACIDS C14, C16 AND C18	<= 11.0 %

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