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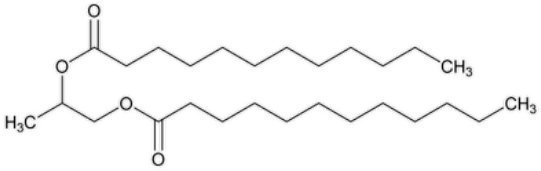
Propylene Glycol Dilaurate



$C_{27}H_{52}O_4$

Lauric acid, diester with propane-1,2-diol;
Propane-1,2-diyl didodecanoate

440.70 CAS RN®: 22788-19-8.

DEFINITION

Propylene Glycol Dilaurate is a mixture of the propylene glycol mono- and diesters of lauric acid. It contains NLT 70.0% of diesters and NMT 30.0% of monoesters.

IDENTIFICATION

- **A. Thin-Layer Chromatographic Identification Test ⟨201⟩**

  Standard solution: 50 mg/mL of USP Propylene Glycol Dilaurate RS in methylene chloride

  Sample solution: 50 mg/mL of Propylene Glycol Dilaurate in methylene chloride

  Developing solvent system: Hexane and ether (3:7)

  Spray reagent: 0.1 mg/mL of rhodamine 6G in alcohol

  Analysis: Apply 200 µg of the *Standard solution* and *Sample solution.* Develop the chromatogram over a path of 15 cm, and dry the plate in a current of air. Spray the plate with *Spray reagent*, and locate the spots on the plate by examination under UV light at a wavelength of 365 nm.

  Acceptance criteria: The R_F values of the principal spots of the *Sample solution* correspond to those of the *Standard solution*.

- **B. Fats and Fixed Oils, *Fatty Acid Composition* ⟨401⟩:** Meets the requirements

ASSAY

- **Procedure**

  Mobile phase: Tetrahydrofuran

  Sample solution: 200 mg of Propylene Glycol Dilaurate in 5 mL of tetrahydrofuran

  Chromatographic system

  (See *Chromatography ⟨621⟩, System Suitability*.)

  Mode: LC

  Detector: Refractive index

  Column: 7-mm × 60-cm; 5-µm packing L21 (100Å)

  [Note—Two 7-mm × 30-cm L21 columns may be used in place of one 60-cm column, provided system suitability requirements are met.]

  Temperature

  Column: 40°

  Detector: 40°

  Flow rate: 1 mL/min

  Injection size: 40 µL

  System suitability

  Sample: *Sample solution*

  [Note—Elution order: diesters, monoesters, propylene glycol.]

Suitability requirements

Relative standard deviation: NMT 1.0% is determined from the monoester peak.

Analysis

Sample: *Sample solution*

Calculate the percentage of monoesters or diesters in the portion of Propylene Glycol Dilaurate taken:

$$\text{Result} = (r_U/r_T) \times (100 - D)$$

r_U = peak response for monoesters or diesters

r_T = sum of the responses of the monoester and diester peaks

D = sum of the percentage content of propylene glycol and the percentage content of free fatty acids

Calculate the percentage content of free fatty acids:

$$\text{Result} = (A/561.1) \times 200$$

A = acid value

Acceptance criteria: NLT 70.0% of diesters and NMT 30.0% of monoesters

IMPURITIES

Inorganic Impurities

• **Articles of Botanical Origin,** *Total Ash* ⟨561⟩**:** NMT 0.1%

Organic Impurities

• **Procedure: Limit of Propylene Glycol**

Mobile phase: Proceed as directed in the *Assay*.

Standard stock solution: 4 mg/mL of USP Propylene Glycol RS in tetrahydrofuran

Standard solutions: Into four 15-mL flasks, introduce respectively 0.25, 0.5, 1.0, and 2.5 mL of *Standard stock solution*, and dilute with tetrahydrofuran to 5.0 mL. In a fifth 15-mL flask, introduce 5.0 mL of *Standard stock solution*.

Sample solution: Use the *Sample solution* from the *Assay*.

Chromatographic system: Proceed as directed in the *Assay*.

Analysis

Samples: *Standard solutions* and *Sample solution*

Prepare a standard curve of peak area versus concentration, in mg/mL, of propylene glycol in the *Standard solutions*. Obtain the concentration, C, in mg/mL, of propylene glycol in the *Sample solution* from the standard curve.

Acceptance criteria: NMT 2.0% of propylene glycol is found.

SPECIFIC TESTS

• **Fats and Fixed Oils,** *Acid Value* ⟨401⟩**:** NMT 4

• **Fats and Fixed Oils,** *Fatty Acid Composition* ⟨401⟩**:** Propylene Glycol Dilaurate exhibits the following composition profile of fatty acids, determined as directed in the chapter.

Fatty Acids	Carbon-Chain Length	Percentage (%)
Caprylic acid	C8	NMT 0.5
Capric acid	C10	NMT 2.0
Lauric acid	C12	NLT 95.0
Myristic acid	C14	NMT 3.0
Palmitic acid	C16	NMT 1.0

• **Fats and Fixed Oils,** *Iodine Value* ⟨401⟩**:** NMT 1

• **Fats and Fixed Oils,** *Saponification Value* ⟨401⟩**:** 230–250

• **Water Determination, *Method Ia* ⟨921⟩:** NMT 1.0%, using a mixture of methanol and methylene chloride (1:1) in place of methanol in the titration vessel

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers, and protect from moisture. No storage requirements are specified.

• **USP Reference Standards ⟨11⟩**
USP Propylene Glycol RS
USP Propylene Glycol Dilaurate RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
PROPYLENE GLYCOL DILAURATE	Documentary Standards Support	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

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