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Propylene Glycol Mono and Dicaprylate

(Title for this monograph—not to become official until December 1, 2026. Prior to December 1, 2026, the current practice of labeling the official article, titled Propylene Glycol Monocaprylate, as Propylene Glycol Monocaprylate (Type I) may be continued. Use of the name Propylene Glycol Mono and Dicaprylate will be permitted as of December 1, 2021; however, the use of this name will not be mandatory until December 1, 2026. The 60-month extension will provide the time needed by manufacturers and users to make necessary changes.)

Change to read:

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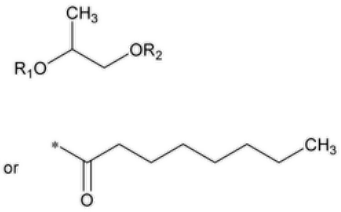

▲ (CN 1-Dec-2023)

$C_{11}H_{22}O_3$ 202.29
(propylene glycol monocaprylate)
$C_{19}H_{36}O_4$ 328.49
(propylene glycol dicaprylate)
Octanoic acid, ester with 1,2-propanediol;
Hydroxypropyl octanoate CAS RN®: 68332-79-6.

DEFINITION

Propylene Glycol Mono and Dicaprylate is a mixture of the propylene glycol monoesters and diesters of fatty acids composed predominantly of caprylic acid. Propylene Glycol Mono and Dicaprylate contains NLT 55.0% and NMT 80.0% monoesters and NLT 20.0% and NMT 45.0% diesters.

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197A

• **B. Thin-Layer Chromatographic Identification Test ⟨201⟩**

Standard solution: 50 mg/mL of USP Propylene Glycol Mono and Dicaprylate RS in methylene chloride

Sample solution: 50 mg/mL of Propylene Glycol Mono and Dicaprylate in methylene chloride

Chromatographic system

Application volume: 10 µL

Developing solvent system: Ether and hexane (70:30)

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

Analysis: 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 from the *Sample solution* correspond to those from the *Standard solution*.

• **C.** It meets the requirements in *Specific Tests* for *Fats and Fixed Oils ⟨401⟩, Procedures, Fatty Acid Composition*.

ASSAY

• **Procedure**

Mobile phase: Tetrahydrofuran

Sample solution: 40 mg/mL of Propylene Glycol Mono and Dicaprylate in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: Refractive index

Column: 7-mm × 60-cm; 5-µm packing L21 (100 Å). [NOTE—Two 7-mm × 30-cm; 5-µm packing L21 columns may be used in place of one 60-cm column, provided *System suitability* requirements are met.]

Temperatures

Column: 40°

Detector: 40°

Flow rate: 1 mL/min

Injection volume: 40 µL

System suitability

Sample: *Sample solution*

[NOTE—The relative retention times with reference to propylene glycol for diesters and monoesters are 0.85 and 0.90, respectively.]

Suitability requirements

Relative standard deviation: NMT 2.0% for the monoester peak

Analysis

Sample: *Sample solution*

Calculate the percentage of monoesters or diesters in the portion of Propylene Glycol Mono and Dicaprylate taken:

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

r_U = peak response for monoesters or diesters

r_T = sum of the peak responses of the monoesters and diesters

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:

$$\text{Result} = (A/561.1) \times 144$$

A = acid value

Acceptance criteria

Monoesters: 55.0%–80.0%

Diesters: 20.0%–45.0%

IMPURITIES

• **LIMIT OF PROPYLENE GLYCOL**

Mobile phase, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard stock solution: 4 mg/mL of USP Propylene Glycol RS in *Mobile phase*

Standard solutions: Into four 5-mL volumetric flasks, introduce 0.25, 0.5, 1.0, and 2.5 mL of *Standard stock solution*, respectively, and dilute with *Mobile phase* to volume. In a fifth 5-mL volumetric flask, introduce 5.0 mL of *Standard stock solution*.

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 of propylene glycol in the *Sample solution* from the standard curve.

Calculate the percentage of free propylene glycol in the portion of Propylene Glycol Mono and Dicaprylate taken:

$$\text{Result} = (C/C_U) \times 100$$

C = concentration of propylene glycol in the *Sample solution* from the standard curve

C_U = concentration of the *Sample solution* (mg/mL)

Acceptance criteria: NMT 1.5%

SPECIFIC TESTS

• **FATS AND FIXED OILS ⟨401⟩, *Procedures, Acid Value*:** NMT 1.5

• **Fats and Fixed Oils ⟨401⟩, *Procedures, Fatty Acid Composition*:** Propylene Glycol Mono and Dicaprylate exhibits the composition profile of fatty acids shown in *Table 1*.

Table 1

Carbon-Chain Length	Number of Double Bonds	Percentage (%)
8	0	≥90.0
10	0	≤3.0
12	0	≤3.0
14	0	≤3.0
16	0	≤1.0

• **Fats and Fixed Oils ⟨401⟩, *Procedures, Iodine Value*:** NMT 1.0

• **Fats and Fixed Oils ⟨401⟩, *Procedures, Saponification Value*:** 285–315

• **Fats and Fixed Oils ⟨401⟩, *Procedures, Peroxide Value*:** NMT 6.0

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

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

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 Mono and Dicaprylate RS
Also known as USP Propylene Glycol Monocaprylate Type I RS

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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