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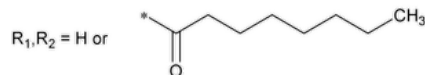
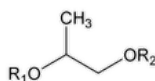
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Propylene Glycol Monocaprylate

Type I of the current official article, titled *Propylene Glycol Monocaprylate*, will be officially titled *Propylene Glycol Mono and Dicaprylate* after December 1, 2026. Type II of the current official article, titled *Propylene Glycol Monocaprylate*, will be officially titled *Propylene Glycol Monocaprylate* after December 1, 2026.

Change to read:

▲



▲ (CN 1-Dec-2023)

$\text{C}_{11}\text{H}_{22}\text{O}_3$ 202.29

(propylene glycol monocaprylate)

$\text{C}_{19}\text{H}_{36}\text{O}_4$ 328.49

(propylene glycol dicaprylate)

Octanoic acid, ester with 1,2-propanediol;

Hydroxypropyl octanoate CAS RN®: 31565-12-5.

DEFINITION

Propylene Glycol Monocaprylate is a mixture of the propylene glycol monoesters and diesters of fatty acids composed predominantly of caprylic acid. Propylene Glycol Monocaprylate contains NLT 90.0% monoesters and NMT 10.0% 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 Monocaprylate RS](#) in methylene chloride

Sample solution: 50 mg/mL of Propylene Glycol Monocaprylate 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 Monocaprylate 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 about 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 Monocaprylate 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: NLT 90.0%

Diesters: NMT 10.0%

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 Monocaprylate 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 Monocaprylate exhibits the composition profile of fatty acids shown in [Table 1](#).