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Propylene Glycol Dicaprylate/Dicaprate

Decanoic acid, mixed diesters with octanoic acid and propylene glycol
CAS RN®: 68583-51-7.

DEFINITION

Propylene Glycol Dicaprylate/Dicaprate is a mixture of the propylene glycol mono- and diesters of caprylic acid (C₈H₁₆O₂) and capric acid (C₁₀H₂₀O₂), the diesters fraction being predominant.

IDENTIFICATION

Change to read:

- A.** [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197F▲](#) (CN 1-MAY-2020)
- B.** [THIN-LAYER CHROMATOGRAPHY IDENTIFICATION TEST \(201\)](#)
Standard solution: 50 mg/mL of [USP Propylene Glycol Dicaprylate/Dicaprate RS](#) in methylene chloride
Sample solution: 50 mg/mL of Propylene Glycol Dicaprylate/Dicaprate in methylene chloride
Application volume: 10 µL, as streaks
Developing solvent system: Ether and hexane (7:3)
Spray reagent: 0.1 mg/mL of rhodamine 6G in alcohol
Analysis
Samples: *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 from the *Sample solution* correspond to those from the *Standard solution*.
- C.** It meets the requirements of the test for [Fats and Fixed Oils \(401\), Fatty Acid Composition](#).

IMPURITIES

Inorganic Impurities

- [ARTICLES OF BOTANICAL ORIGIN, Total Ash \(561\)](#): NMT 0.1%
- ALKALINE IMPURITIES**
Sample: 2.0 g of Propylene Glycol Dicaprylate/Dicaprate
Analysis: Dissolve the *Sample* in a mixture of 1.5 mL of alcohol and 3.0 mL of ether. Add 0.05 mL of bromophenol blue TS.
Acceptance criteria: NMT 0.15 mL of 0.01 N hydrochloric acid is required in order to change the color of the indicator to yellow.

SPECIFIC TESTS

- [FATS AND FIXED OILS, Acid Value \(401\)](#): NMT 0.2
- [FATS AND FIXED OILS, Fatty Acid Composition \(401\)](#): Propylene Glycol Dicaprylate/Dicaprate exhibits the composition profile of fatty acids shown in the following table:

Carbon-Chain Length	Number of Double Bonds	Percentage (%)
6	0	≤2.0
8	0	50.0–80.0

Carbon-Chain Length	Number of Double Bonds	Percentage (%)
10	0	20.0–50.0
12	0	≤3.0
14	0	≤1.0

- **FATS AND FIXED OILS, *Hydroxyl Value* (401):** NMT 10
- **FATS AND FIXED OILS, *Iodine Value* (401):** NMT 1.0
- **FATS AND FIXED OILS, *Peroxide Value* (401):** NMT 1.0
- **FATS AND FIXED OILS, *Saponification Value* (401):** 320–340
- **FATS AND FIXED OILS, *Unsaponifiable Matter* (401):** NMT 0.5%, determined on 5.0 g
- **WATER DETERMINATION, *Method Ia* (921):** NMT 0.1%, 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 specified.
- **USP REFERENCE STANDARDS (11):**
[USP Propylene Glycol Dicaprylate/Dicaprate RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE	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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