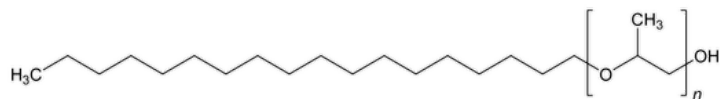


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Polypropylene Glycol 11 Stearyl Ether



$C_{18}H_{38}O(C_3H_6O)_n$, where the average value of n is 11.
 Poly[oxy(methyl-1,2-ethanediyl)], α -octadecyl- ω -hydroxy-;
 Polypropylene glycol monooctadecyl ether;
 Polyoxypropylene 11 stearyl ether
 CAS RN[®]: 25231-21-4.

Change to read:

DEFINITION

Polypropylene Glycol 11 Stearyl Ether is a mixture of ethers of polypropylene glycol with linear alcohols, mainly stearyl alcohol, obtained by the reaction of stearyl alcohol with propylene oxide. It may contain some free polypropylene glycol and various amounts of free stearyl alcohol.

The number of moles of propylene oxide reacted per mole of stearyl alcohol is 11 (nominal value). ▲ It contains NLT 96.0% and NMT 104.0% of polypropylene glycol 11 stearyl ether, calculated on the anhydrous basis. ▲ (NF 1-May-2023) A suitable antioxidant may be added.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197A
- **B.** It meets the requirements in *Specific Tests* for [Fats and Fixed Oils \(401\)](#), [Procedures, Hydroxyl Value](#).
- **C.** It meets the requirements in *Specific Tests* for [Fats and Fixed Oils \(401\)](#), [Procedures, Saponification Value](#).
- **D. VISCOSITY**

Analysis: Follow the procedures in [Viscosity—Capillary Methods \(911\)](#), [Method I](#). Immerse the viscometer in a water or oil bath stabilized at 20°. The measurement can also be carried out with a rotational rheometer or viscometer¹ following the procedures in [Viscosity—Rotational Methods \(912\)](#), [Method III](#). The temperature under the test condition is at 20°. The samples are tested in the controlled stress mode with a shear stress increasing from 0–100 Pa for 120 s with 100 measured points. Each sample is equilibrated in the measuring gap of 0.052 mm for 60 s. The dynamic viscosity is determined from the slope of the flow curve.

Acceptance criteria: 83–95 mPa · s

Add the following:

▲ ASSAY

• PROCEDURE

Solution A: 0.05% [98 percent formic acid](#) in a mixture of [methanol](#) and [acetonitrile](#) (80:20)

Solution B: [Tetrahydrofuran](#)

Mobile phase: A mixture of *Solution A* and *Solution B* (95:5)

System suitability solution: 1.0 mg/mL of [USP Polypropylene Glycol 11 Stearyl Ether RS](#) and 0.02 mg/mL of [USP Stearyl Alcohol RS](#) in *Mobile phase*

Standard solution: 1.0 mg/mL of [USP Polypropylene Glycol 11 Stearyl Ether RS](#) in *Mobile phase*

Sample solution: 1.0 mg/mL of Polypropylene Glycol 11 Stearyl Ether in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: Refractive index

Column: 4.6-mm × 25-cm; 5-μm packing [L7](#)

Temperatures

Column: 30°

Detector: 30°

Flow rate: 1.0 mL/min

Injection volume: 20 μL

Run time: 20 min

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The approximate relative retention time of stearyl alcohol with reference to polypropylene glycol 11 stearyl ether is 0.8.]

Suitability requirements

Resolution: NLT 1.5 between stearyl alcohol and polypropylene glycol 11 stearyl ether, *System suitability solution*

Tailing factor: NMT 2.0 for polypropylene glycol 11 stearyl ether, *Standard solution*

Relative standard deviation: NMT 1% for polypropylene glycol 11 stearyl ether, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of polypropylene glycol 11 stearyl ether in the portion of Polypropylene Glycol 11 Stearyl Ether taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak area of polypropylene glycol 11 stearyl ether from the *Sample solution*

r_S = peak area of polypropylene glycol 11 stearyl ether from the *Standard solution*

C_S = concentration of [USP Polypropylene Glycol 11 Stearyl Ether RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Polypropylene Glycol 11 Stearyl Ether in the *Sample solution* (mg/mL)

Acceptance criteria: 96.0%–104.0% on the anhydrous basis ▲ (NF 1-May-2023)

IMPURITIES

• **RESIDUE ON IGNITION (281).**

Sample: 1.0 g

Acceptance criteria: NMT 0.3%

• **LIMIT OF FREE PROPYLENE OXIDE**

Propylene oxide stock solution: Accurately weigh 45 g of [polyethylene glycol 200](#) kept at 8°–15° and add 1.0 g of propylene oxide. Carefully mix the solution by swirling, ensuring a homogenous solution. Add further [polyethylene glycol 200](#) until the total weight is 50.0 g and mix again. Allow the solution to reach room temperature. Dilute 0.5 g of this solution up to 100.0 mL in water. Note the exact mass. [NOTE—*Propylene oxide stock solution* is stable for 1 month, if stored at –20°.]

Propylene oxide standard solution: Dilute 10.0 mL of *Propylene oxide stock solution* with [water](#) to 100.0 mL.

Propionaldehyde stock solution: Accurately weigh 0.1 g of [propionaldehyde](#) into a volumetric flask and dilute with [water](#) to 100.0 mL.

Sample solution A: Accurately weigh 1.0 g of Polypropylene Glycol 11 Stearyl Ether into a 20-mL headspace vial. Add 0.5 mL of [water](#) kept at 8°–15° and seal the vial immediately with a polytetrafluoroethylene (PTFE)-coated silicon membrane and an aluminum cap. Mix carefully.

Sample solution B: Accurately weigh 1.0 g of Polypropylene Glycol 11 Stearyl Ether into a 20-mL headspace vial. Add 0.5 mL of *Propylene oxide standard solution* kept at 8°–15° and seal the vial immediately with a PTFE-coated silicon membrane and an aluminum cap. Mix carefully.

Reference solution: Add 50.0 mL of *Propylene oxide standard solution* kept at 8°–15° to a volumetric flask and add 0.5 mL of *Propionaldehyde stock solution* kept at 8°–15°. Dilute with [water](#) to 100.0 mL. Transfer 0.5 mL of this solution into a 20-mL headspace vial and seal the vial immediately with a PTFE-coated silicon membrane and an aluminum cap.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: GC, equipped with a headspace injector

Detector: Flame ionization

Column: 0.32-mm × 60-m fused-silica; coated with 5-μm film of phase [G1](#)

Temperatures

Injection port: 150°

Detector: 250°