

Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: NF Monographs
 DocId: GUID-D1612D3D-E94E-42D5-A09E-B6D036CAD1D0_2_en-US
 DOI: https://doi.org/10.31003/USPNF_M46356_02_01
 DOI Ref: 85jet

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Polyoxyl Lauryl Ether

$\text{CH}_3(\text{CH}_2)_{11}(\text{OCH}_2\text{CH}_2)_n\text{OH}$, $n = 3-23$
 Polyethylene glycol monolauryl ether
 CAS RN®: 9002-92-0.

DEFINITION

Polyoxyl Lauryl Ether is a mixture of the monolauryl ethers of mixed polyethylene glycols, the average polymer length being equivalent to NLT 3 and NMT 23 oxyethylene units (nominal value). It contains various amounts of free lauryl alcohol, and it may contain some free polyethylene glycols.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197F ▲](#) (CN 1-MAY-2020)

Sample: Use a thin film of melted Polyoxyl Lauryl Ether if the material is a solid.

Acceptance criteria: Meets the requirements

- **B. PROCEDURE**

Sample: 0.1 g

Analysis: Dissolve or disperse the *Sample* in 5 mL of alcohol, and add 10 mL of diluted hydrochloric acid, 5 mL of barium chloride TS, and 10 mL of phosphomolybdic acid solution (1 in 10).

Acceptance criteria: A precipitate is formed.

- **C.** It meets the requirements of the test for [Fats and Fixed Oil, Hydroxyl Values \(401\)](#).

IMPURITIES

Organic Impurities

- **PROCEDURE: LIMIT OF FREE ETHYLENE OXIDE AND DIOXANE**

Analysis: Proceed as directed in [Ethylene Oxide and Dioxane, Method I \(228\)](#).

Acceptance criteria

Ethylene oxide: NMT 1 µg/g (ppm)

Dioxane: NMT 10 µg/g (ppm)

SPECIFIC TESTS

- **ALKALINITY**

Sample: 2.0 g of Polyoxyl Lauryl Ether

Analysis: Dissolve the *Sample* in a hot mixture of 10 mL of alcohol and 10 mL of water. Add 0.05 mL of bromothymol blue TS, and titrate with 0.1 N hydrochloric acid to a yellow endpoint.

Acceptance criteria: NMT 0.5 mL of 0.1 N hydrochloric acid is required.

- **APPEARANCE OF SOLUTION:** 5.0 g of Polyoxyl Lauryl Ether in 50.0 mL of alcohol. The solution is not more intensely colored than a solution prepared immediately before use by mixing 12.0 mL of ferric chloride CS, 5.0 mL of cobaltous chloride CS, and 2.0 mL of cupric sulfate CS with dilute hydrochloric acid (10 g/L) to make 50.0 mL, and diluting 12.5 mL of this solution with dilute hydrochloric acid (10 g/L) to make 100.0 mL. Make the comparison by viewing the substance and the solution downward in matched color-comparison tubes against a white surface (see [Color and Achromicity \(631\)](#)).

- [ARTICLES OF BOTANICAL ORIGIN, Total Ash \(561\)](#): NMT 0.2%, determined on 2.0 g

- [FATS AND FIXED OILS, Acid Value \(401\)](#): NMT 1.0, determined on 5.0 g

- **FATS AND FIXED OILS, [Hydroxyl Value \(401\)](#)**: Within the ranges specified in the accompanying table

Oxyethylene Units/Molecule (Nominal Value)	Hydroxyl Value
3	165–185
4	145–165
5	130–140
9	90–100
10	85–95
12	73–83
15	64–74
20–23	40–60

- **FATS AND FIXED OILS, [Iodine Value \(401\)](#)**: NMT 2.0
- **FATS AND FIXED OILS, [Saponification Value \(401\)](#)**: NMT 3.0, determined on 10.0 g
- **WATER DETERMINATION, [Method I \(921\)](#)**: NMT 3.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE**: Preserve in tight containers, and store in a cool, dry place.
- **LABELING**: Label it to indicate the average nominal number of oxyethylene units.
- **USP REFERENCE STANDARDS (11)**
[USP Polyoxyl 4 Lauryl Ether RS](#)
[USP Polyoxyl 9 Lauryl Ether RS](#)
[USP Polyoxyl 23 Lauryl Ether RS](#)

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

Topic/Question	Contact	Expert Committee
POLYOXYL LAURYL ETHER	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:

Pharmacopeial Forum: Volume No. PF 36(4)

Current DocID: GUID-D1612D3D-E94E-42D5-A09E-B6D036CAD1D0_2_en-US

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