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Polyoxyl 40 Hydrogenated Castor Oil

Polyethylene glycol 40 hydrogenated castor oil;
Polyoxyethylene 40 hydrogenated castor oil
CAS RN®: 61788-85-0.

DEFINITION

Polyoxyl 40 Hydrogenated Castor Oil contains mainly the trihydroxystearate ester of ethoxylated glycerol, with smaller amounts of polyethylene glycol hydroxystearate and the corresponding free glycols. It results from the reaction of glycerol tri-hydroxystearate with 40–45 mol of ethylene oxide.

IDENTIFICATION

• A. IDENTITY BY FATTY ACID COMPOSITION

Diluent: Chloroform

Standard solution 1: 0.4 mg/mL each of methyl palmitate, methyl arachidate, methyl 12-ketostearate, methyl stearate, and methyl 12-hydroxystearate, from [USP Methyl Palmitate RS](#), [methyl arachidate](#), methyl 12-ketostearate, [USP Methyl Stearate RS](#), and [USP Methyl 12-Hydroxystearate RS](#), in *Diluent*

Standard solution 2: 4 mg/mL each of methyl stearate and methyl 12-hydroxystearate from [USP Methyl Stearate RS](#) and [USP Methyl 12-Hydroxystearate RS](#) in *Diluent*

Sample solution: Transfer 140 mg of Polyoxyl 40 Hydrogenated Castor Oil to a 10-mL screw-cap test tube, add 3.0 mL of *Diluent*, and mix well. Add 0.5 mL of 0.5 M sodium methoxide in methanol,¹ and mix with the sample. Allow the reaction to proceed at room temperature for 2 h. After 2 h, add 5 mL of water, and mix. Centrifuge the test tube at 2000 × g for 10 min at 4° until a clear organic layer forms. Separate the organic layer, and remove the aqueous layer. Place an aliquot of the organic layer into an autosampler vial.

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.32-mm × 30-m fused silica capillary; bonded with a 0.25-µm layer of phase [G16](#)

Temperatures

Injection port: 240°

Detector: 250°

Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)	Total Time (min)
80	0	80	1	1
80	30	140	0	3
140	20	180	5	10
180	2	250	10	66

Carrier gas: Hydrogen
Flow rate: 5.0 mL/min, constant flow mode
Injection volume: 1.0 µL
Injection type: Split, split ratio 120:1 or 60:1
Liner: Single gooseneck liner with deactivated glass wool
Run time: 55 min

System suitability

Sample: *Standard solution 1*
[NOTE—For relative retention times, see [Table 2](#).]

Table 2

Component	Relative Retention Time
Methyl palmitate (C16:0)	0.27
Methyl stearate (C18:0)	0.37
Methyl arachidate (C20:0)	0.54
Methyl 12-ketostearate	0.85
Methyl 12-hydroxystearate	1.00

Suitability requirements

Resolution: NLT 5 between any two adjacent peaks
Relative standard deviation: NMT 2.0% for the peak area ratio of methyl 12-hydroxystearate to methyl 12-ketostearate

Analysis

Samples: *Standard solution 1, Standard solution 2, and Sample solution*
Calculate the relative response factor, *F*, for methyl 12-hydroxystearate:

$$F = (r_S/r_R) \times (C_R/C_S)$$

- r_S* = peak area of methyl stearate from *Standard solution 2*
- r_R* = peak area of methyl 12-hydroxystearate from *Standard solution 2*
- C_R* = concentration of [USP Methyl 12-Hydroxystearate RS](#) in *Standard solution 2* (mg/mL)
- C_S* = concentration of [USP Methyl Stearate RS](#) in *Standard solution 2* (mg/mL)

Correct the peak area of methyl 12-hydroxystearate in the *Sample solution* by multiplying by *F*.
Calculate the percentage of each fatty acid component in the portion of Polyoxyl 40 Hydrogenated Castor Oil taken:

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

- r_U* = peak area of each individual fatty acid methyl ester except for the uncorrected peak area of methyl 12-hydroxystearate (or the corrected peak area of methyl 12-hydroxystearate), from the *Sample solution*
- r_T* = sum of all the peak areas, excluding the solvent and methyl 12-hydroxystearate peaks and including the corrected peak area of methyl 12-hydroxystearate, from the *Sample solution*

Acceptance criteria: Polyoxyl 40 Hydrogenated Castor Oil exhibits the composition profile of fatty acids shown in [Table 3](#).

Table 3