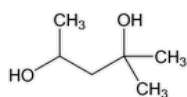


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Hexylene Glycol

Change to read:



$C_6H_{14}O_2$ ▲118.18 ▲ (NF 1-May-2020)

2,4-Pentanediol, 2-methyl;

2-Methyl-2,4-pentanediol;

▲2-Methylpentane-2,4-diol ▲ (NF 1-May-2020) CAS RN®: 107-41-5.

DEFINITION

Change to read:

Hexylene Glycol ▲contains NLT 98.0% and NMT 102.0% of 2-methylpentane-2,4-diol, calculated on the anhydrous basis. ▲ (NF 1-May-2020)

IDENTIFICATION

Change to read:

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

Sample: Undried specimen

Acceptance criteria: Meets the requirements

Add the following:

▲• B. Chromatographic Identity

Analysis: Examine the chromatograms from the Assay.

Acceptance criteria: The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*. ▲ (NF 1-May-2020)

ASSAY

Add the following:

▲• Procedure

Diluent: [Methanol](#)

Internal standard solution: 1.0 mg/mL of [USP Propylene Glycol RS](#) (internal standard) in *Diluent*

System suitability solution: 0.1 mg/mL of diacetone alcohol and 1.0 mg/mL of [USP Hexylene Glycol RS](#) in *Internal standard solution*

Standard solution: 1.0 mg/mL of [USP Hexylene Glycol RS](#) in *Internal standard solution*

Sample solution: 1.0 mg/mL of Hexylene Glycol in *Internal standard solution*

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.32-mm × 60-m capillary; bonded with a 1.0-μm layer of phase G1

Temperatures

Injection port: 200°

Detector: 300°

Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
40	0	40	3
40	15	200	15

Carrier gas: Helium

Pressure: 15 psi (constant pressure mode)

Injection volume: 1.0 µL

Injection type: Split ratio, 100:1

Liner: Ultra inert liner with glass wool, low pressure drop¹

System suitability

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

[NOTE—The approximate relative retention times are listed in [Table 2](#).]

Suitability requirements

Resolution: NLT 5 between hexylene glycol and diacetone alcohol, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 2.0% for the peak response ratio of hexylene glycol to the internal standard, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of hexylene glycol in the portion of the sample taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of hexylene glycol to the internal standard (peak response of hexylene glycol/peak response of the internal standard) from the *Sample solution*

R_S = peak response ratio of hexylene glycol to the internal standard (peak response of hexylene glycol/peak response of the internal standard) from the *Standard solution*

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

C_U = concentration of Hexylene Glycol in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous basis ▲ (NF 1-May-2020)

IMPURITIES

Change to read:

▲ ORGANIC IMPURITIES

Diluent and Chromatographic system: Proceed as directed in the Assay.

Sensitivity solution: 0.01 mg/mL of [USP Hexylene Glycol RS](#) in *Diluent*

System suitability solution: 0.2 mg/mL of [USP Acetone RS](#) and 0.2 mg/mL of [USP 2-Propanol RS](#) in *Diluent*

Standard solution: 0.02 mg/mL of [USP Hexylene Glycol RS](#) in *Diluent*

Sample solution: 20.0 mg/mL of Hexylene Glycol in *Diluent*

System suitability

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

[NOTE—The approximate relative retention times are listed in [Table 2](#).]

Suitability requirements

Resolution: NLT 1.5 between the acetone peak and the 2-propanol peak, *System suitability solution*

Relative standard deviation: NMT 5.0%, determined from the hexylene glycol peak, *Standard solution*

Signal-to-noise ratio: NLT 10, determined from the hexylene glycol peak, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each individual impurity in the portion of the sample taken: