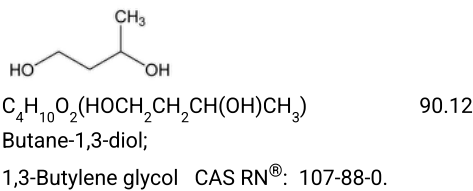


Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: NF Monographs
DocId: GUID-30F0A581-2276-4675-B692-2EFF127A78FF_2_en-US
DOI: https://doi.org/10.31003/USPNF_M947_02_01
DOI Ref: 7s6t0

© 2025 USPC
Do not distribute

Butylene Glycol



DEFINITION

Butylene Glycol contains NLT 98.0% and NMT 102.0% of butane-1,3-diol ($C_4H_{10}O_2$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- A.** [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197F▲](#) (CN 1-MAY-2020)
- B. CHROMATOGRAPHIC IDENTITY**
Analysis: Proceed as directed in the Assay.
Acceptance criteria: The retention time of butane-1,3-diol in the *Sample solution* corresponds to that in the *Standard solution*.

ASSAY

- PROCEDURE**
Standard solution: 1.0 mg/mL of [USP Butane-1,3-diol RS](#) and 1.0 mg/mL of [USP Propylene Glycol RS](#) (internal standard) in methanol
Sample solution: 1.0 mg/mL of Butylene Glycol and 1.0 mg/mL of [USP Propylene Glycol RS](#) (internal standard) in methanol
Chromatographic system
(See [Chromatography \(621\), System Suitability.](#))
Mode: GC
Detector: Flame ionization
Column: 0.53-mm × 30-m capillary; bonded with a 1.0-μm layer of phase G16 or G47
Temperatures
Detector: 240°
Injection port: 230°
Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
40	0	40	3
40	10	80	0
80	5	130	2
130	10	170	0
170	25	240	0

Carrier gas: Hydrogen
Flow rate: 10 mL/min
Injection volume: 1.0 μL

Injection type: Split injection; split ratio is 2:1.

Liner: Single gooseneck liner with wool

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for propylene glycol and butane-1,3-diol are 1.00 and 1.22, respectively.]

Suitability requirements

Resolution: NLT 15 between propylene glycol and butane-1,3-diol

Tailing factor: 0.8–2.0

Relative standard deviation: NMT 2% for the peak response ratio of butane-1,3-diol to the internal standard

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of butane-1,3-diol in the portion of Butylene Glycol taken:

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

R_U = peak response ratio of butane-1,3-diol to the internal standard (peak response of butane-1,3-diol/peak response of the internal standard) from the *Sample solution*

R_S = peak response ratio of butane-1,3-diol to the internal standard (peak response of butane-1,3-diol/peak response of the internal standard) from the *Standard solution*

C_S = concentration of [USP Butane-1,3-diol RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.05% determined on 2 g

• **LIMIT OF LEAD**

[NOTE—For the preparation of all aqueous solutions and for the rinsing of glassware before use, use water that has been passed through a strong-acid, strong-base, mixed-bed ion-exchange resin. For digestion, use acid-cleaned, high-density polyethylene, polypropylene, polytetrafluoroethylene, or quartz tubes. Select all reagents to have as low a content of lead as practicable, and store all reagent solutions in borosilicate glass containers. Cleanse glassware before use by soaking in warm 8 N nitric acid for 30 min and rinsing with deionized water. Store final diluted solutions in acid-cleaned plastic or polytetrafluoroethylene tubes or bottles.]

Matrix modifier solution: 200 mg/mL of magnesium nitrate. Just before use, transfer 1.0 mL of this solution to a 10-mL volumetric flask, and dilute with 5% nitric acid to volume.

Alternative matrix modifier solution: Just before use, add 0.3 mL of commercially available 10,000 µg/mL palladium standard solution and 5 mL of commercially available 10,000 µg/mL magnesium nitrate standard solution to 9.7 mL of 5% nitric acid, and mix well. [NOTE—*Alternative matrix modifier solution* can be used to replace the *Matrix modifier solution*. If the alternative solution is used, then the air-ashing step in the furnace program (see [Table 2](#)) can be omitted.]

Table 2

Step	Temperature (°)	Ramp (s)	Hold Time (s)	Gas	Gas Flow Rate (mL/min)	Read (s)
Dry	200	20	30	Argon	300	—
Char (ash)	750	40	40	Air ^a	300	—
Cool down	20	1	60	Argon	300	—
Atomize	1800	0	10	Argon	Stop flow	10
Clean	2600	1	7	Argon	300	—
Cool down	20	1	5	Argon	300	—

^a If *Matrix modifier solution* is used, air ashing must be used in the experiment. If *Alternative matrix modifier solution* is used, air can be substituted with argon.

Lead nitrate stock solution: Dissolve 159.8 mg of lead nitrate in 100 mL of water to which has been added 1 mL of nitric acid, and then dilute with water to 1000 mL. Prepare and store this solution in glass containers free from soluble lead salts.