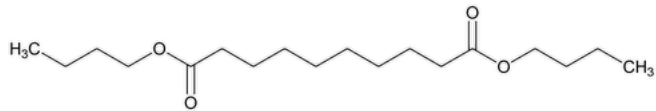


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Dibutyl Sebacate



$\text{CH}_3(\text{CH}_2)_3\text{OOC}(\text{CH}_2)_8\text{COO}(\text{CH}_2)_3\text{CH}_3$ $\text{C}_{18}\text{H}_{34}\text{O}_4$ 314.46
Decanedioic acid, 1,10-dibutyl ester;
Dibutyl 1,10-decanedioate;
Sebacic acid di-*n*-butyl ester CAS RN®: 109-43-3.

DEFINITION

Dibutyl Sebacate consists of esters of *n*-butyl alcohol and saturated dibasic acids, principally sebacic acid. It contains NLT 92.0% and NMT 102.0% of dibutyl sebacate ($\text{C}_{18}\text{H}_{34}\text{O}_4$).

IDENTIFICATION

Change to read:

- A. **SPECTROSCOPIC IDENTIFICATION TESTS** (197), **Infrared Spectroscopy: 197F** (CN 1-MAY-2020)
Sample: Undried specimen
Acceptance criteria: Meets the requirements
- B. The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

- PROCEDURE**
Internal standard solution: 0.9 mg/mL of methyl heptadecanoate in alcohol
Standard solution: 1.0 mg/mL of [USP Dibutyl Sebacate RS](#) in the *Internal standard solution*
Sample solution: 1.0 mg/mL of Dibutyl Sebacate in the *Internal standard solution*
Chromatographic system
(See [Chromatography \(621\), System Suitability](#).)
Mode: GC
Detector: Flame ionization
Column: 0.32-mm × 30-m fused silica column, coated with a 0.25-μm film of phase G2
Temperature
Detector: 300°
Injection port: 300°
Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
150	—	150	5
150	10	250	5

Carrier gas: Helium
Linear velocity: 50 cm/s
Injection volume: 1 μL
Injection type: Split injection, split ratio is about 30:1
Run time: 20 min
System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for dibutyl sebacate and methyl heptadecanoate are 1.0 and 0.9, respectively.]

Suitability requirements

Resolution: NLT 2.0 between methyl heptadecanoate and dibutyl sebacate

Relative standard deviation: NMT 2.0% for the peak response ratio of dibutyl sebacate to methyl heptadecanoate

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of dibutyl sebacate ($C_{18}H_{34}O_4$) in the portion of Dibutyl Sebacate taken:

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

R_U = peak response ratio of dibutyl sebacate to methyl heptadecanoate from the *Sample solution*

R_S = peak response ratio of dibutyl sebacate to methyl heptadecanoate from the *Standard solution*

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

C_U = concentration of Dibutyl Sebacate in the *Sample solution* (mg/mL)

Acceptance criteria: 92.0%–102.0%

SPECIFIC TESTS

- [SPECIFIC GRAVITY \(841\)](#): 0.935–0.939 at 20°
- [REFRACTIVE INDEX \(831\)](#): 1.429–1.441
- [FATS AND FIXED OILS, Acid Value \(401\)](#): NMT 0.1
- [FATS AND FIXED OILS, Saponification Value \(401\)](#): 352–360

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers. Store at room temperature. Protect from moisture.
- [USP REFERENCE STANDARDS \(11\)](#)
[USP Dibutyl Sebacate RS](#)

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

Topic/Question	Contact	Expert Committee
DIBUTYL SEBACATE	Documentary Standards Support	SE2020 Simple Excipients

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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