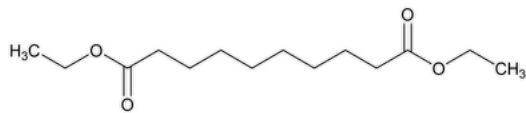


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Diethyl Sebacate



$\text{CH}_3\text{CH}_2\text{OOC}(\text{CH}_2)_8\text{COOCH}_2\text{CH}_3$
 $\text{C}_{14}\text{H}_{26}\text{O}_4$ 258.35
Decanedioic acid, 1,10-diethyl ester;
Diethyl 1,10-decanedioate CAS RN®: 110-40-7.

DEFINITION

Diethyl Sebacate consists of the diester of alcohol (ethanol) and sebacic acid. It contains NLT 98.0% and NMT 102.0% of diethyl sebacate ($\text{C}_{14}\text{H}_{26}\text{O}_4$).

IDENTIFICATION

Change to read:

- **A.** **▲** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Infrared Spectroscopy*: **197F**▲ (CN 1-MAY-2020)
- **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 [n-heptane](#)
Standard solution: 1.0 mg/mL of [USP Diethyl Sebacate RS](#) in the *Internal standard solution*
Sample solution: 1.0 mg/mL of Diethyl Sebacate in the *Internal standard solution*

Chromatographic system

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

Mode: GC
Detector: Flame ionization
Column: 0.53-mm × 30-m fused silica capillary; 1.5-μm layer of phase G1
Temperatures
Injection port: 300°
Detector: 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, 3:1
System suitability
Sample: *Standard solution*

[NOTE—The relative retention times for diethyl sebacate and methyl heptadecanoate are 1.0 and 1.2, respectively.]

Suitability requirements

Resolution: NLT 2.0 between diethyl sebacate and methyl heptadecanoate

Relative standard deviation: NMT 2.0%, ratio of the peak response of diethyl sebacate to that of methyl heptadecanoate

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of diethyl sebacate ($C_{14}H_{26}O_4$) in the portion of Diethyl Sebacate taken:

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

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

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

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

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

Acceptance criteria: 98.0%–102.0%

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.10%

SPECIFIC TESTS

- [SPECIFIC GRAVITY \(841\)](#): 0.958–0.968 at 20°
- [REFRACTIVE INDEX \(831\)](#): 1.435–1.437 at 20°
- [FATS AND FIXED OILS \(401\)](#), [Procedures, Acid Value](#): NMT 0.5
- [FATS AND FIXED OILS \(401\)](#), [Procedures, Iodine Value](#): NMT 0.5

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, and store in a cool, dry, and well-ventilated place.
- [USP REFERENCE STANDARDS \(11\)](#)
[USP Diethyl Sebacate RS](#)

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

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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