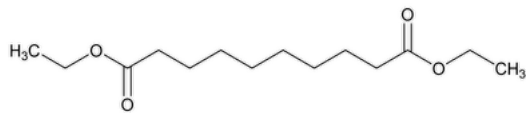


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# Diethyl Sebacate



$\text{CH}_3\text{CH}_2\text{OOC}(\text{CH}_2)_8\text{COOCH}_2\text{CH}_3$   
 $\text{C}_{14}\text{H}_{26}\text{O}_4$  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 | <a href="#">Documentary Standards Support</a> | SE2020 Simple Excipients |

**Chromatographic Database Information:** [Chromatographic Database](#)

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