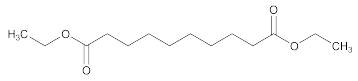
Diethyl Sebacate



$CH_3CH_2OOC(CH_2)_8COOCH_2CH_3$

$C_{14}H_{26}O_4$ 258.35

Decanedioic acid, 1,10-diethyl ester;
Diethyl 1,10-decanedioate [110-40-7].

DEFINITION

Change to read:

Diethyl Sebacate consists of the diester of alcohol (ethanol) and sebacic acid. It contains NLT 98.0% and NMT •102.0%• (IRA 1-Mar-2018) of diethyl sebacate ($C_{14}H_{26}O_4$).

IDENTIFICATION

- **A. INFRARED ABSORPTION ⟨197F⟩**
- **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

Change to read:

- **PROCEDURE**

Internal standard solution: 0.9 mg/mL of methyl heptadecanoate in •*n*-heptane• (IRA 1-Mar-2018)
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%• (IRA 1-Mar-2018)

IMPURITIES

- **RESIDUE ON IGNITION ⟨281⟩:** NMT 0.10%

Delete the following:

- •• **HEAVY METALS,** *Method II* ⟨**231**⟩**:** NMT 20 ppm• (Official 1-Jan-2018)

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

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