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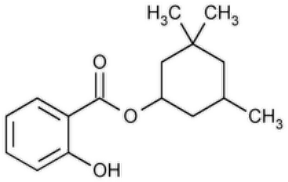
Homosalate



$C_{16}H_{22}O_3$ 262.34

Benzoic acid, 2-hydroxy, 3,3,5-trimethylcyclohexyl ester;

3,3,5-Trimethylcyclohexyl salicylate CAS RN®: 118-56-9; UNII: V06SV4M95S.

DEFINITION

Homosalate contains NLT 90.0% and NMT 110% of $C_{16}H_{22}O_3$, calculated on the as-is basis.

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197F**▲ (CN 1-May-2020)

ASSAY

• **Procedure**

Standard solution: 5.0 mg/mL of USP Homosalate RS in chloroform

Sample solution: 5.0 mg/mL of Homosalate in chloroform

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: GC

Detector: Flame ionization

Column: 0.53-mm × 30-m column coated with a 1-µm film of G27

Temperature

Injector: 270°

Detector: 270°

Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
70	6	220	5

Carrier gas: Hydrogen

Flow rate: 6 mL/min

Injection size: 1 µL

Split ratio: 1:10

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for the *cis*-isomer and the *trans*-isomer are about 0.98 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.0 between the *cis*-isomer and the *trans*-isomer

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of homosalate ($C_{16}H_{22}O_3$) in the portion of Homosalate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = sum of the peak responses for the *cis*- and *trans*-isomers from the *Sample solution*

r_S = sum of the peak responses for the *cis*- and *trans*-isomers from the *Standard solution*

C_S = concentration of USP Homosalate RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110% on the as-is basis

SPECIFIC TESTS

- **SPECIFIC GRAVITY ⟨841⟩:** 1.049–1.053
- **REFRACTIVE INDEX ⟨831⟩:** 1.516–1.519 at 20°

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- **USP REFERENCE STANDARDS ⟨11⟩**
  USP Homosalate RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
HOMOSALATE	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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