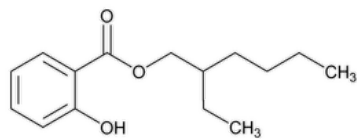


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Octisalate



$C_{15}H_{22}O_3$ 250.33
Benzoic acid, 2-hydroxy-, 2-ethylhexyl ester;
2-Ethylhexyl salicylate CAS RN[®]: 118-60-5; UNII: 4X49Y0596W.

DEFINITION
Octisalate contains NLT 95.0% and NMT 105.0% of octisalate ($C_{15}H_{22}O_3$), calculated on the as-is basis.

IDENTIFICATION
Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Infrared Spectroscopy*: 197A or 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**
Standard solution: 20 mg/mL of [USP Octisalate RS](#) in [tert-butyl methyl ether](#)
Sample solution: 20 mg/mL of Octisalate in [tert-butyl methyl ether](#)
Chromatographic system
(See [Chromatography \(621\)](#), *System Suitability*.)
Mode: GC
Detector: Flame ionization
Column: 0.32-mm × 25-m; coated with a 0.1-μm film of phase G1
Temperatures
Injector: 240°
Detector: 260°
Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
60	8	240	10

Carrier gas: Helium
Flow rate: 6 mL/min
Injection volume: 1 μL
Injection type: Split; split ratio 50:1. [NOTE—Split ratio can be modified to optimize the performance.]
System suitability
Sample: *Standard solution*
Suitability requirements

Resolution: NLT 1.0 between octisalate and any other peak

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of octisalate ($C_{15}H_{22}O_3$) in the portion of Octisalate taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 95.0%–105.0% on the as-is basis

IMPURITIES

• ORGANIC IMPURITIES

Standard solution, Sample solution, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Octisalate taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of each impurity from the *Sample solution*

r_T = sum of all the peak responses from the *Sample solution*

Acceptance criteria

Individual impurities: NMT 0.5%

Total impurities: NMT 2.0%

SPECIFIC TESTS

- **SPECIFIC GRAVITY (841):** 1.011–1.016
- **REFRACTIVE INDEX (831):** 1.500–1.503 at 20°
- **ACIDITY**

Sample solution: 5.0 mL of measured Octisalate

Titrimetric system

Mode: Direct titration

Titrant: 0.1 N [sodium hydroxide](#)

Endpoint detection: Visual

Analysis: Transfer 50 mL of alcohol to a suitable container, add 1 mL of [phenol red TS](#), and add sufficient *Titrant* to obtain a persistent pink color. Transfer 50 mL of this solution to a suitable container, add the *Sample solution*, mix, and titrate with *Titrant*.

Acceptance criteria: NMT 0.2 mL of 0.1 N sodium hydroxide per milliliter of Octisalate is required for neutralization.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- **USP REFERENCE STANDARDS (11).**
[USP Octisalate RS](#)

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

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

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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