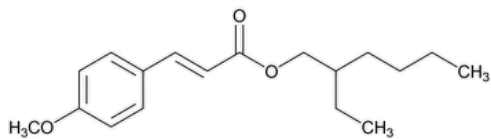


Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-5BA0A497-1386-4B81-981B-318235094FA1_5_en-US
DOI: https://doi.org/10.31003/USPNF_M58316_05_01
DOI Ref: 05epo

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Octinoxate



$C_{18}H_{26}O_3$ 290.40
2-Propenoic acid, 3-(4-methoxyphenyl)-, 2-ethylhexyl ester;
2-Ethylhexyl *p*-methoxycinnamate CAS RN®: 5466-77-3; UNII: 4Y5P7MUD51.

DEFINITION
Octinoxate contains NLT 95.0% and NMT 105.0% of octinoxate ($C_{18}H_{26}O_3$), 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 octinoxate peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

- **PROCEDURE**
System suitability stock solution: 5% (v/v) [USP Benzyl Benzoate RS](#) in [acetone](#)
System suitability solution: 50 mg/mL of [USP Octinoxate RS](#) in *System suitability stock solution*
Standard solution: 50 mg/mL of [USP Octinoxate RS](#) in [acetone](#)
Sample solution: Transfer 5 mL of Octinoxate to a 100-mL volumetric flask, and dilute with [acetone](#) to volume.
Chromatographic system
(See [Chromatography \(621\)](#), [System Suitability](#).)
Mode: GC
Detector: Flame ionization
Column: 0.32-mm × 25-m; 0.25-μm thickness of phase [G1](#)
Carrier gas: Helium
Temperatures
Injection port: 250°
Detector: 300°
Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
80	22	300	10

Flow rate: 2 mL/min
Injection volume: 1 μL
Injection type: Split ratio, 85:1
System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for benzyl benzoate and octinoxate are about 0.68 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 20 between benzyl benzoate and octinoxate, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of octinoxate ($C_{18}H_{26}O_3$) in the portion of Octinoxate taken:

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

r_U = peak response of octinoxate from the *Sample solution*

r_S = peak response of octinoxate from the *Standard solution*

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

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

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

IMPURITIES

• ORGANIC IMPURITIES

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

Sample solution: Transfer 5 mL of Octinoxate to a 100-mL volumetric flask, and dilute with [acetone](#) to volume.

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Octinoxate 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

Any individual impurity: NMT 0.5%

Total impurities: NMT 2.0%

SPECIFIC TESTS

• **SPECIFIC GRAVITY (841):** 1.005–1.013

• **REFRACTIVE INDEX (831):** 1.542–1.548 at 20°

• ACIDITY

Sample: 5 mL of Octinoxate

Analysis: Add 50 mL of [alcohol](#) to the *Sample*, and mix. Add 4 drops of [phenolphthalein TS](#), and titrate with 0.1 N [sodium hydroxide](#).

Acceptance criteria: NMT 0.8 mL of 0.1 N [sodium hydroxide](#) is required.

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers, and store in a cool place.

• **USP REFERENCE STANDARDS (11).**

[USP Benzyl Benzoate RS](#)

Benzoic acid, phenylmethyl ester.

$C_{14}H_{12}O_2$ 212.24

[USP Octinoxate RS](#)