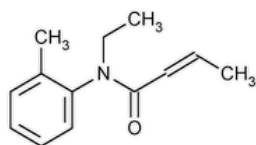


Status: Currently Official on 14-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-91083B74-D85F-4998-AED5-42FB17957574_2_en-US
 DOI: https://doi.org/10.31003/USPNF_M20640_02_01
 DOI Ref: 903yg

© 2025 USPC
 Do not distribute

Crotamiton



$C_{13}H_{17}NO$ 203.28

2-Butenamide, *N*-ethyl-*N*-(2-methylphenyl)-.

N-Ethyl-*o*-crotonotoluidide CAS RN®: 483-63-6; UNII: D6S4O4XD0H.

» Crotamiton is a mixture of *cis* and *trans* isomers containing not less than 97.0 percent and not more than 103.0 percent of $C_{13}H_{17}NO$.

Packaging and storage—Preserve in tight, light-resistant containers.

USP REFERENCE STANDARDS (11)—

[USP Crotamiton RS](#)

Identification—

Change to read:

A: [▲Spectroscopic Identification Tests \(197\), Infrared Spectroscopy: 197F](#)▲ (CN 1-May-2020)

Change to read:

B: [▲Spectroscopic Identification Tests \(197\), Ultraviolet-Visible Spectroscopy: 197U](#)▲ (CN 1-May-2020) —

Solution: 20 µg per mL.

Medium: cyclohexane.

C: To about 10 mL of a saturated solution in water add a few drops of potassium permanganate TS: a brown color is produced, and a brown precipitate is formed on standing.

SPECIFIC GRAVITY (841): between 1.008 and 1.011 at 20°.

REFRACTIVE INDEX (831): between 1.540 and 1.543 at 20°.

RESIDUE ON IGNITION (281): not more than 0.1%.

Bound halogen—Place 4 drops in a 3-mm (ID) test tube, and add calcium oxide to a height of 1 cm. Heat the tube in a flame, starting from the top, until the reaction is complete, then ignite for a short time. Transfer the contents to a beaker containing 10 mL of water, acidify with nitric acid, and filter. To the filtrate add 0.2 mL of silver nitrate solution (1 in 60): any opalescence obtained is not more than that obtained from a blank solution treated in the same manner.

Assay—Transfer about 50 mg of Crotamiton, accurately weighed, to a 100-mL volumetric flask, add cyclohexane to volume, and mix. Transfer 10.0 mL of this solution to a 250-mL volumetric flask, dilute with cyclohexane to volume, and mix. Determine the absorbance of this solution and of a solution of [USP Crotamiton RS](#) in the same medium having a known concentration of about 20 µg per mL in 1-cm cells at the wavelength of maximum absorbance at about 242 nm, with a suitable spectrophotometer, using cyclohexane as the blank. Calculate the quantity, in mg, of $C_{13}H_{17}NO$ in the Crotamiton taken by the formula:

$$2.5C(A_U/A_S)$$

in which *C* is the concentration, in µg per mL, of [USP Crotamiton RS](#) in the Standard solution; and *A_U* and *A_S* are the absorbances of the assay solution and the Standard solution, respectively.

Topic/Question	Contact	Expert Committee
CROTAMITON	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-91083B74-D85F-4998-AED5-42FB17957574_2_en-US

DOI: https://doi.org/10.31003/USPNE_M20640_02_01

DOI ref: [903yg](#)

OFFICIAL