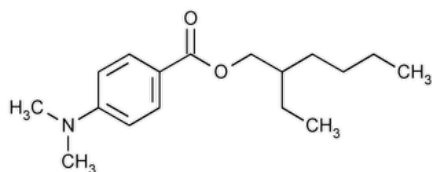


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Padimate O



$C_{17}H_{27}NO_2$ 277.40

Benzoic acid, 4-(dimethylamino)-, 2-ethylhexyl ester;

2-Ethylhexyl *p*-(dimethylamino)benzoate CAS RN®: 21245-02-3; UNII: Z11006CMUZ.

DEFINITION

Padimate O contains NLT 97.0% and NMT 102.0% of padimate O ($C_{17}H_{27}NO_2$).

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 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

Mobile phase: Methanol, water, and glacial acetic acid (850:150:0.5)

Standard solution: 0.1 mg/mL of [USP Padimate O RS](#) in methanol

Sample solution: 0.1 mg/mL of Padimate O in methanol

Chromatographic system

(See [Chromatography \(621\), System Suitability.](#))

Mode: LC

Detector: UV 308 nm

Column: 4.6-mm × 15-cm; 5-μm packing L1

Flow rate: 1.5 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of padimate O ($C_{17}H_{27}NO_2$) in the portion of Padimate O 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 Padimate O RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 97.0%–102.0%

IMPURITIES

• ORGANIC IMPURITIES

Sample solution: 10 mg/mL of Padimate O in chloroform

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: GC

Detector: Flame ionization

Column: 3-mm × 1.8-m stainless steel packed with 10% liquid phase G9 on support S1A

Carrier gas: Helium

Column temperature: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
150	10	250	10

Injection volume: 2 µL

Analysis

Sample: *Sample solution*

Calculate the percentage of the total impurities in the portion of Padimate O taken:

$$[\Sigma r_i / (\Sigma r_i + r_U)] \times 100$$

r_i = individual impurity peak response from the *Sample solution*

r_U = Padimate O peak response from the *Sample solution*

Acceptance criteria

Total impurities: NMT 2.0%

SPECIFIC TESTS

- [SPECIFIC GRAVITY \(841\)](#): 0.990–1.000
- [REFRACTIVE INDEX \(831\)](#): 1.5390–1.5430
- [FATS AND FIXED OILS, Acid Value \(401\)](#): NMT 1.0
- [FATS AND FIXED OILS, Saponification Value \(401\)](#)

Analysis: Proceed as directed in the chapter, except to maintain reflux for 4 h.

Acceptance criteria: 195–215

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.
- **USP REFERENCE STANDARDS (11)**

[USP Padimate O RS](#)

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

Topic/Question	Contact	Expert Committee
PADIMATE O	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

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