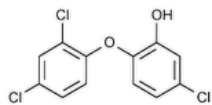


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Triclosan



$C_{12}H_7Cl_3O_2$ 289.54
Phenol, 5-chloro-2-(2,4-dichlorophenoxy)-;
2,4,4'-Trichloro-2'-hydroxydiphenyl ether CAS RN®: 3380-34-5; UNII: 4NM5039Y5X.

DEFINITION
Triclosan contains NLT 97.0% and NMT 103.0% of triclosan ($C_{12}H_7Cl_3O_2$), calculated on the anhydrous basis.

IDENTIFICATION
Change to read:

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Infrared Spectroscopy*: 197K ▲ or 197A ▲ (USP 1-Dec-2021)
- **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
Change to read:

- **PROCEDURE**
Standard solution: 0.4 mg/mL of [USP Triclosan RS](#) in [ethyl acetate](#)
Sample solution: 0.4 mg/mL of Triclosan in [ethyl acetate](#)
Chromatographic system
(See [Chromatography \(621\)](#), *System Suitability*.)
Mode: GC
Detector: Flame ionization
Column: 0.53-mm × 15-m; ▲ coated with a 1.0-μm film of ▲ (USP 1-Dec-2021) phase [G3](#)
Temperatures
Injection port: ▲ ▲ (USP 1-Dec-2021) 200°
Detector: 260°
Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
34	20	140	0
140	4	240	NLT 5

Carrier gas: Helium
Pressure: 6 psi
Injection volume: 2 μL
System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of triclosan ($C_{12}H_7Cl_3O_2$) in the portion of Triclosan taken:

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

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

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

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

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

Acceptance criteria: 97.0%–103.0% on the anhydrous basis

IMPURITIES

• **ORGANIC IMPURITIES**

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

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Sample: *Sample solution*

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

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

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

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

Acceptance criteria

Individual impurities: NMT 0.1%

Total impurities: NMT 0.5%

Change to read:

- **LIMIT OF 1,3,7-TRICHLORODIBENZO-*p*-DIOXIN, 2,8-DICHLORODIBENZO-*p*-DIOXIN, 2,8-DICHLORODIBENZOFURAN, AND 2,4,8-TRICHLORODIBENZOFURAN**

Mobile phase: Acetonitrile, water, and glacial acetic acid (70: 30: 0.1)

Standard solution: Use [USP Triclosan Related Compounds Mixture A RS](#)

Sample solution: Transfer 2.0 g of Triclosan into a screw-capped centrifuge tube. Add 5 mL of 2 N potassium hydroxide, and shake for 10 min to dissolve. Add 3 mL of [n-hexane](#), shake for 10 min, and allow the phases to separate. Transfer the organic layer to a suitable container, add another 3 mL of [n-hexane](#) to the aqueous layer, shake for 10 min, and allow the phases to separate. Transfer the organic layer to the previous extract, discard the aqueous layer, add 3 mL of 2 N potassium hydroxide to the combined organic layers, shake for 10 min, and allow the phases to separate. Discard the aqueous layer, add another 3 mL of 2 N potassium hydroxide to the combined organic layers, shake for 10 min, and allow the phases to separate. Transfer the organic layer to a suitable container, and evaporate with the aid of a stream of nitrogen to dryness. Dissolve the residue in 1.0 mL of [methanol](#).

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; ▲5-μm▲ (USP 1-Dec-2021) packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 20 μL

System suitability