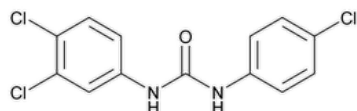


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# Triclocarban



$C_{13}H_9Cl_3N_2O$  315.58

Urea, *N*-(4-chlorophenyl)-*N'*-(3,4-dichlorophenyl)-;

3,4,4'-Trichlorocarbanilide;

1-(4-Chlorophenyl)-3-(3,4-dichlorophenyl)urea CAS RN®: 101-20-2; UNII: BGG1Y1ED0Y.

## DEFINITION

Triclocarban contains NLT 97.0% and NMT 103.0% of triclocarban ( $C_{13}H_9Cl_3N_2O$ ), calculated on the dried basis.

## IDENTIFICATION

**Change to read:**

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (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:** Acetonitrile, methanol, water, and glacial acetic acid (400:500:300:1.5)

**System suitability solution:** 0.1 mg/mL each of [USP Triclocarban RS](#), [USP Triclocarban Related Compound A RS](#), and [USP Triclocarban Related Compound C RS](#) in acetonitrile

**Standard solution:** 0.1 mg/mL of [USP Triclocarban RS](#) in acetonitrile. The solution is stable for 12 h.

**Sample solution:** 0.1 mg/mL of Triclocarban in acetonitrile. The solution is stable for 12 h.

### Chromatographic system

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

**Mode:** LC

**Detector:** UV 265 nm

**Column:** 4.6-mm × 25-cm; 5-μm packing L1

**Flow rate:** 2 mL/min

**Injection volume:** 20 μL

### System suitability

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

[NOTE—The relative retention times for triclocarban related compound A, triclocarban, and triclocarban related compound C are 0.7, 1.0, and 1.6, respectively.]

### Suitability requirements

**Resolution:** NLT 2.0 between triclocarban related compound A and triclocarban, NLT 2.0 between triclocarban and triclocarban related compound C, *System suitability solution*

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

### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of triclocarban ( $C_{13}H_9Cl_3N_2O$ ) in the portion of Triclocarban 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 Triclocarban RS](#) in the *Standard solution* (mg/mL)

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

**Acceptance criteria:** 97.0%–103.0% on the dried basis

## IMPURITIES

### • ORGANIC IMPURITIES

**Mobile phase:** Acetonitrile, methanol, water, and glacial acetic acid (370:380:250:1)

**Internal standard solution:** 0.12 mg/mL of *p*-nitrochlorobenzene in methanol

**Standard solution:** 2 µg/mL each of [USP Triclocarban RS](#), [USP Triclocarban Related Compound A RS](#), [USP Triclocarban Related Compound C RS](#), [USP Triclocarban Related Compound D Mixture RS](#), and 2.4 µg/mL of *p*-nitrochlorobenzene from the *Internal standard solution*. Dissolve and dilute with methanol to volume.

**Sample solution:** 0.2 mg/mL of Triclocarban and 2.4 µg/mL of *p*-nitrochlorobenzene from the *Internal standard solution*. Dissolve and dilute with methanol to volume.

### Chromatographic system

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

**Mode:** LC

**Detector:** UV 254 nm

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

**Column temperature:** 40°

**Flow rate:** 1.3 mL/min

**Injection volume:** 20 µL

### System suitability

**Sample:** *Standard solution*

#### Suitability requirements

**Signal-to-noise ratio:** NLT 10 for triclocarban related compound A, triclocarban related compound C, and triclocarban related compound D mixture

**Relative standard deviation:** NMT 2.0% for triclocarban

### Analysis

**Samples:** *Standard solution* and *Sample solution*

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

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

$R_U$  = peak response ratio of each impurity to the internal standard from the *Sample solution*

$R_S$  = peak response ratio of corresponding specified impurity to the internal standard from the *Standard solution* (use the triclocarban peak response ratio to calculate for any individual impurity)

$C_S$  = concentration of each impurity in the *Standard solution* (µg/mL)

$C_U$  = concentration of Triclocarban in the *Sample solution* (µg/mL)

**Acceptance criteria:** See [Table 1](#).

**Table 1**

| Name                                         | Relative Retention Time | Acceptance Criteria, NMT (%) |
|----------------------------------------------|-------------------------|------------------------------|
| <i>p</i> -Nitrochlorobenzene <sup>a</sup>    | 0.45                    | —                            |
| Triclocarban related compound A <sup>b</sup> | 0.64                    |                              |