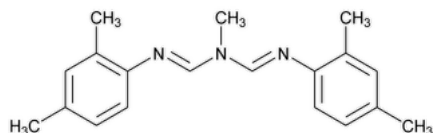


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Delete the following:

▲Amitraz



$C_{19}H_{23}N_3$ 293.41

Methanimidamide, *N'*-(2,4-dimethylphenyl)-*N*-[[[(2,4-dimethylphenyl)imino]methyl]-*N*-methyl-;
N-Methyl-*N'*-2,4-xylyl-*N*-(*N*-2,4-xylylformimidoyl)formamidine;
N-Methylbis(2,4-xylyliminomethyl)amine CAS RN®: 33089-61-1; UNII: 33IAH5017S.

DEFINITION

Amitraz contains NLT 95.0% and NMT 101.5% of amitraz ($C_{19}H_{23}N_3$), calculated on the anhydrous basis.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS.** (197), *Infrared Spectroscopy*: 197A, 197K, or 197M
- **B.** The retention time of the amitraz peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Internal standard solution: 0.7% v/v solution of squalane in methyl acetate

Standard solution: 5.0 mg/mL of [USP Amitraz RS](#) in *Internal standard solution*

Sample solution: 5.0 mg/mL of Amitraz in *Internal standard solution*

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.53-mm × 15-m fused silica; coated with a 1.5-μm layer of liquid phase G9

Temperatures

Detector: 300°

Inlet: 230°

Column: 220°

Carrier gas: Helium

Flow rate: 12 mL/min

Injection volume: 1 μL

System suitability

Sample: *Standard solution*

[NOTE—The elution order is amitraz followed by squalane.]

Suitability requirements

Resolution: NLT 3.0 between amitraz and squalane

Relative standard deviation: NMT 2.0% from the peak area ratio of amitraz to squalane

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of amitraz ($C_{19}H_{23}N_3$) in the portion of Amitraz taken:

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

R_U = peak response ratio of amitraz and squalane from the *Sample solution*

R_S = peak response ratio of amitraz and squalane from the *Standard solution*

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

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

Acceptance criteria: 95.0%–101.5% on the anhydrous basis

IMPURITIES

• **RESIDUE ON IGNITION (281):** NMT 0.2%

• ORGANIC IMPURITIES

Standard solution: 0.05 mg/mL of 2,4-dimethylaniline, 1.0 mg/mL of [USP Amitraz Related Compound A RS](#), 0.5 mg/mL of [USP Amitraz Related Compound B RS](#), and 1.0 mg/mL of [USP Amitraz Related Compound C RS](#) in methyl acetate

Sample solution: 50.0 mg/mL of Amitraz in methyl acetate

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.53-mm × 10-m fused silica; coated with a 5-μm layer of liquid phase G27

Temperatures

Detector: 300°

Inlet: 230°

Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
125	0	125	5
125	5	270	15

Carrier gas: Helium

Flow rate: 12 mL/min

Injection volume: 1 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 3.0 between amitraz related compound A and amitraz related compound B

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each of amitraz related compounds A, B, and C in the portion of Amitraz taken:

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

r_U = peak response of each individual impurity from the *Sample solution*

r_S = peak response of the corresponding related compound from the *Standard solution*

C_S = concentration of the corresponding related compound in the *Standard solution* (mg/mL)

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

Calculate the percentage of 2,4-dimethylaniline and any other individual impurity in the portion of Amitraz taken:

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

r_U = peak response of each individual impurity from the *Sample solution*

r_S = peak response of 2,4-dimethylaniline from the *Standard solution*

C_S = concentration of 2,4-dimethylaniline in the *Standard solution* (mg/mL)

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

Acceptance criteria: See [Table 2](#). The reporting level for impurities is 0.05%.

Table 2