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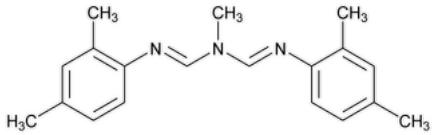
Delete the following:

▲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

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
2,4-Dimethylaniline	0.11	0.1
Amitraz related compound A	0.35	2
Amitraz related compound B	0.40	1
Amitraz related compound C	0.86	2
Amitraz	1.0	—
Any other individual impurity	—	0.1

SPECIFIC TESTS

• **Water Determination, *Method I*⟨921⟩:** NMT 0.1%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **Labeling:** Label it to indicate that it is for veterinary use only.

• **USP Reference Standards ⟨11⟩**

USP Amitraz RS

USP Amitraz Related Compound A RS

2,4-Dimethylphenyl formamide;
N-(2,4-Dimethylphenyl)formamide.
$C_9H_{11}NO$ 149.19

USP Amitraz Related Compound B RS

2,4-Dimethylphenyl *N*-methyl-formamidine;
N'-(2,4-Dimethylphenyl)-*N*-methylformimidamide.
$C_{10}H_{14}N_2$ 162.23

USP Amitraz Related Compound C RS

Bisformamidine analog;
N,*N*'-Bis(2,4-dimethylphenyl)formimidamide.
$C_{17}H_{20}N_2$ 252.35▲ (USP 1-Dec-2024)

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
AMITRAZ	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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