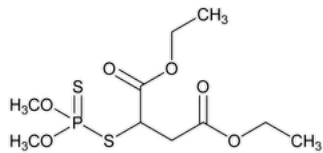


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Malathion

Change to read:



$C_{10}H_{19}O_6PS_2$ Δ 330.35 Δ (USP 1-May-2022)
Butanedioic acid, [(dimethoxyphosphinothioyl)-thio]-, diethyl ester, ($\pm$);
Diethyl ($\pm$)-mercaptosuccinate, S-ester with O,O-dimethyl phosphorodithioate;
 Δ Diethyl 2-[(dimethoxyphosphorothioyl)thio]succinate Δ (USP 1-May-2022) CAS RN[®]: 121-75-5; UNII: U5N7SU872W.

DEFINITION
Malathion contains NLT 98.0% and NMT 102.0% of malathion ($C_{10}H_{19}O_6PS_2$).

IDENTIFICATION
• **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197F

Add the following:
 Δ • **B.** The retention time of the malathion peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. Δ
(USP 1-May-2022)

ASSAY
Change to read:
• **PROCEDURE**
 Δ **Solution A:** [Water](#)
Solution B: [Acetonitrile](#)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	55	45
20	55	45
25	5	95
30	5	95
30.1	55	45
35	55	45

Diluent: [Acetonitrile](#) and [water](#) (75:25)
Standard solution: 2 mg/mL of [USP Malathion RS](#) in *Diluent*
Sample solution: 2 mg/mL of Malathion in *Diluent*
Chromatographic system
(See [Chromatography \(621\)](#), [System Suitability](#).)
Mode: LC
Detector: UV 210 nm
Column: 4.6-mm $\times$ 15-cm; 5- μ m packing [L1](#)
Column temperature: 35°
Flow rate: 1 mL/min

Injection volume: 20 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 malathion ($C_{10}H_{19}O_6PS_2$) in the portion of Malathion taken:

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

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

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

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

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

▲ (USP 1-May-2022)

Acceptance criteria: 98.0%–102.0%

IMPURITIES

Delete the following:

▲• **LIMIT OF ISOMALATHION**

Mobile phase: Methanol and water (50:30)

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

Sample solution: 20 mg/mL of Malathion in methanol

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4-mm × 30-cm; 10-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for isomalathion and malathion are about 0.5 and 1.0, respectively.]

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of isomalathion in the portion of Malathion taken:

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

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

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

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

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

Acceptance criteria: NMT 0.3%▲ (USP 1-May-2022)

Add the following:

▲• **ORGANIC IMPURITIES**

Solution A: [Acetonitrile](#) and [water](#) (43:57)

Solution B: [Acetonitrile](#)

Mobile phase: See [Table 2](#).

Table 2