



Edition: BP 2025 (Ph. Eur. 11.6 update)

Malathion Lotion

[General Notices](#)

Action and use

Organophosphorus insecticide.

DEFINITION

Malathion Lotion is a *cutaneous solution*. It contains Malathion in a suitable vehicle and may contain an alcohol.

The lotion complies with the requirements stated under Liquids for Cutaneous Application and with the following requirements.

Content of malathion, $C_{10}H_{19}O_6PS_2$

90.0 to 110.0% of the stated amount.

IDENTIFICATION

In the Assay, the chromatogram obtained with solution (1) shows a peak with the same retention time as that of the principal peak in the chromatogram obtained with solution (2).

TESTS

Related substances

Carry out the method for [liquid chromatography, Appendix III D](#), using the following solutions in a mixture of 1 volume of [water](#) and 3 volumes of [acetonitrile](#) (solvent A).

- (1) Dilute a quantity of the preparation being examined with sufficient solvent A to produce a solution containing 0.2% w/v of Malathion.
- (2) Dilute 1 volume of solution (1) to 500 volumes.
- (3) 0.0002% w/v each of [malathion impurity A EPCRS](#) and [malathion impurity B EPCRS](#).
- (4) Dilute 1 volume of solution (2) to 2 volumes.

CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (15 cm × 4.6 mm) packed with [octadecylsilyl silica gel for chromatography](#) (10 μm) (Nucleosil C18 is suitable).
- (b) Use isocratic elution and the mobile phase described below.
- (c) Use flow rate of 1 mL per minute.
- (d) Use a column temperature 35°.
- (e) Use a detection wavelength of 210 nm.
- (f) Inject 20 μL of each solution.

MOBILE PHASE

When the chromatograms are recorded under the prescribed conditions, the relative retentions with reference to Malathion (retention time = about 16 minutes) are: impurity B = about 0.2 and impurity A = about 0.3.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the [resolution factor](#) between the peaks due to impurity A and impurity B is at least 2.0.

LIMITS

In the chromatogram obtained with solution (1):

the area of any peak corresponding to malathion impurity A is not greater than three times the area of the corresponding peak in the chromatogram obtained with solution (3) (0.3%);

the area of any peak corresponding to malathion impurity B is not greater than the area of the corresponding peak in the chromatogram obtained with solution (3) (0.1%);

the area of any other [secondary peak](#) is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (0.2%);

the sum of the areas any other [secondary peaks](#) is not greater than five times the area of the principal peak in the chromatogram obtained with solution (2) (1.0%).

Disregard any peak with an area less than the area of the principal peak in the chromatogram obtained with solution (4) (0.1%).

ASSAY

Carry out the method for [liquid chromatography, Appendix III D](#), using the following solutions in a mixture of 1 volume of [water](#) and 3 volumes of [acetonitrile](#) (solvent B).

- (1) Dilute a quantity of the preparation being examined with sufficient solvent B to produce a solution containing 0.2% w/v of Malathion.
- (2) 0.2% w/v of [malathion EPCRS](#).
- (3) 0.0002% w/v each of [malathion impurity A EPCRS](#) and [malathion impurity B EPCRS](#).

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the [resolution factor](#) between the peaks due to impurity A and impurity B is at least 2.0.

DETERMINATION OF CONTENT

Calculate the content of $C_{10}H_{19}O_6PS_2$ using the declared content of $C_{10}H_{19}O_6PS_2$ in [malathion EPCRS](#).

STORAGE

Malathion Lotion should be stored in an airtight container, protected from light.

LABELLING

The solution may be flammable.

IMPURITIES

The impurities limited by the requirements of this monograph include those listed under Malathion.