



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

## Malathion Shampoo

### [General Notices](#)

### Action and use

Organophosphorus insecticide.

### DEFINITION

Malathion Shampoo contains Malathion in a suitable vehicle.

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

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

95.0 to 105.0% 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](#).

#### 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 a 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

45 volumes of [acetonitrile](#) and 55 volumes of [water](#).

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 of 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 half the area of the principal peak in the chromatogram obtained with solution (3) (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 Shampoo should be stored in an airtight container, protected from light.

## IMPURITIES

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

