



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

Macrogol Stearyl Ether



[General Notices](#)

(Ph. Eur. monograph 1340)

Action and use

Non-ionic surfactant.

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DEFINITION

Mixture of ethers obtained by ethoxylation of stearyl alcohol. It may contain some free macrogols and various amounts of free stearyl alcohol. The number of moles of ethylene oxide reacted per mole of stearyl alcohol is 2 to 20 (nominal value).

CHARACTERS

Appearance

White or yellowish-white, waxy, unctuous mass, pellets, microbeads or flakes.

Solubility

- macrogol stearyl ether with 2 moles of ethylene oxide reacted per mole: practically insoluble in water, soluble in ethanol (96 per cent) with heating and in methylene chloride;
- macrogol stearyl ether with 10 moles of ethylene oxide reacted per mole: soluble in water and in ethanol (96 per cent);
- macrogol stearyl ether with 20 moles of ethylene oxide reacted per mole: soluble in water, in ethanol (96 per cent) and in methylene chloride.

After melting, it solidifies at about 45 °C.

IDENTIFICATION

- Hydroxyl value (see Tests).
- Iodine value (see Tests).

- C. Saponification value (see Tests).
- D. Thin-layer chromatography ([2.2.27](#)).

Test solution Dissolve 10.0 g in a mixture of 1 volume of [water R](#) and 9 volumes of [methanol R](#) and dilute to 75 mL with the same mixture of solvents. Add 60 mL of [heptane R](#) and shake for 3 min. The formation of foam can be reduced by the addition of a few drops of [ethanol \(96 per cent\) R](#). Filter the upper layer through [anhydrous sodium sulfate R](#), wash the filter with 3 quantities, each of 10 mL, of [heptane R](#) and evaporate the combined filtrates to dryness. Dissolve 50 mg of the residue in 10 mL of [methanol R](#) (the solution may be opalescent).

Reference solution Dissolve 25 mg of [stearyl alcohol CRS](#) in [methanol R](#) and dilute to 25 mL with the same solvent.

Plate [TLC silica gel plate R](#).

Mobile phase [ethyl acetate R](#).

Application 20 µL.

Development Over a path of 15 cm.

Drying In air.

Detection Spray with vanillin-sulfuric acid reagent prepared as follows: dissolve 0.5 g of [vanillin R](#) in 50 mL of [ethanol \(96 per cent\) R](#) and dilute to 100 mL with [sulfuric acid R](#); allow to dry in air; heat at about 130 °C for 15 min and allow to cool in air.

Results The chromatogram obtained with the test solution shows several spots; one of these spots corresponds to the principal spot in the chromatogram obtained with the reference solution.

E. Dissolve or disperse 0.1 g in 5 mL of [ethanol \(96 per cent\) R](#), add 2 mL of [water R](#), 10 mL of [dilute hydrochloric acid R](#), 10 mL of [barium chloride solution R1](#) and 10 mL of a 100 g/L solution of [phosphomolybdic acid R](#). A precipitate is formed.

TESTS

Appearance of solution

The solution is not more intensely coloured than reference solution BY₅ ([2.2.2, Method II](#)).

Dissolve 5.0 g in [ethanol \(96 per cent\) R](#) and dilute to 50 mL with the same solvent.

Alkalinity

Dissolve 2.0 g in a hot mixture of 10 mL of [ethanol \(96 per cent\) R](#) and 10 mL of [water R](#). Add 0.1 mL of [bromothymol blue solution R1](#). Not more than 0.5 mL of [0.1 M hydrochloric acid](#) is required to change the colour of the indicator to yellow.

[Acid value \(2.5.1\)](#)

Maximum 1.0, determined on 5.0 g.

[Hydroxyl value \(2.5.3, Method A\)](#)

Number of moles of ethylene oxide reacted per mole (nominal value)	Hydroxyl value
2	150 - 180
10	75 - 90
20	40 - 60

Iodine value ([2.5.4, Method A](#))

Maximum 2.0.

Saponification value ([2.5.6](#))

Maximum 3.0, determined on 10.0 g.

Ethylene oxide and dioxan ([2.4.25](#))

Maximum 1 ppm of ethylene oxide and maximum 10 ppm of dioxan.

Water ([2.5.12](#))

Maximum 3.0 per cent, determined on 1.00 g.

STORAGE

In an airtight container.

LABELLING

The label states the number of moles of ethylene oxide reacted per mole of stearyl alcohol (nominal value).

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