



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

Macrogol Stearate



[General Notices](#)

(Ph. Eur. monograph 1234)

Action and use

Non-ionic surfactant.

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DEFINITION

Mixture of monoesters and diesters of mainly stearic (octadecanoic) acid and/or palmitic (hexadecanoic) acid and macrogols. It may be obtained by ethoxylation or by esterification of macrogols with stearic acid 50 (type I) or stearic acid 95 (type II) (see [Stearic acid \(1474\)](#)). It may contain free macrogols. The average polymer length is equivalent to 6 to 100 ethylene oxide units per molecule (nominal value).

CHARACTERS

Appearance

White or slightly yellowish, waxy mass.

Solubility

Soluble in ethanol (96 per cent) and in 2-propanol. Macrogol stearate corresponding to a product with 6-9 units of ethylene oxide per molecule is practically insoluble, but freely dispersible in water and miscible with fatty oils and with waxes. Macrogol stearate corresponding to a product with 20-100 units of ethylene oxide per molecule is soluble in water and practically insoluble in fatty oils and in waxes.

IDENTIFICATION

- A. Saponification value (see Tests).
- B. Composition of fatty acids (see Tests).

TESTS

Alkalinity

Dissolve 2.0 g in [ethanol \(96 per cent\) R](#) and dilute to 20 mL with the same solvent. To 2 mL of this solution add 0.05 mL of [phenol red solution R](#). The solution is not red.

Melting point (2.2.15)

See Table 1234.-1.

Melt about 10 g at 80-90 °C. Introduce a sufficient amount of the substance into the tube by capillary action to form a column of the prescribed height. Allow to stand at 0 °C for 2 h.

Acid value (2.5.1)

Maximum 4.0, determined on 2.0 g.

Hydroxyl value (2.5.3, Method A)

See Table 1234.-1.

Iodine value (2.5.4)

Maximum 2.0.

Saponification value (2.5.6)

See Table 1234.-1.

Table 1234.-1

Ethylene oxide units per molecule (nominal value)	Melting point (°C)	Hydroxyl value	Saponification value
6	26 - 37	80 - 110	85 - 115
8 - 9	26 - 35	80 - 105	88 - 100
20	33 - 40	50 - 62	46 - 56
32	46 - 50	20 - 40	30 - 45
40 - 50	38 - 52	23 - 40	20 - 35
100	48 - 60	15 - 30	5 - 20

Composition of fatty acids

Gas chromatography ([2.4.22, Method C](#)).

Composition of the fatty acid fraction of the substance:

Type of fatty acid used	Composition of fatty acids
Macrogol stearate	Stearic acid 50 Stearic acid : 40.0 per cent to 60.0 per cent,

	Type of fatty acid used	Composition of fatty acids
type I		Sum of the contents of palmitic and stearic acids: not less than 90.0 per cent.
Macrogol stearate type II	Stearic acid 95	<u>Stearic acid</u> : 90.0 per cent to 99.0 per cent, Sum of the contents of palmitic and stearic acids: not less than 96.0 per cent.

Ethylene oxide and dioxan (2.4.25)

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

Water (2.5.12)

Maximum 3.0 per cent, determined on 0.50 g. Use as the solvent a mixture of equal volumes of anhydrous methanol R and methylene chloride R.

Total ash (2.4.16)

Maximum 0.3 per cent, determined on 1.0 g.

STORAGE

In an airtight container.

LABELLING

The label states:

- the number of ethylene oxide units per molecule (nominal value);
- the type of macrogol stearate.

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