



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

Macrogol Oleate



[General Notices](#)

(Ph. Eur. monograph 1618)

Action and use

Non-ionic surfactant.

Ph Eur

DEFINITION

A mixture of monoesters and diesters of mainly oleic (*cis*-9-octadecenoic) acid and macrogols. It may be obtained by ethoxylation of [Oleic acid \(0799\)](#) or by esterification of macrogols with oleic acid of animal or vegetable origin. It may contain free macrogols. The average polymer length is equivalent to 5-6 or 10 moles of ethylene oxide per mole (nominal value). A suitable antioxidant may be added.

CHARACTERS

Appearance

Slightly yellowish, viscous liquid.

Solubility

Dispersible in water, soluble in ethanol (96 per cent) and in 2-propanol, dispersible in oils, miscible with fatty oils and with waxes.

[Refractive index](#)

About 1.466.

IDENTIFICATION

First identification: A, C.

Second identification: A, B.

- A. Saponification value (see Tests).
- B. Thin-layer chromatography ([2.2.27](#)).

Test solution To 20 mg add 10 mL of [methylene chloride R](#) and mix.

Plate [TLC silica gel F₂₅₄ plate R](#).

Mobile phase 25 per cent V/V solution of [concentrated ammonia R](#), [2-propanol R](#) (20:80 V/V).

Application 10 µL.

Development Over a path of 15 cm.

Drying In air.

Detection Spray with [potassium iodobismuthate solution R4](#); examine the plate about 10 min later.

Results The chromatogram obtained shows 3 principal spots, corresponding, in order of increasing R_F value, to free macrogol, macrogol mono-oleate and macrogol dioleate.

- C. 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.

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

Maximum 2.0.

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

See Table 1618.-1.

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

See Table 1618.-1.

[Peroxide value \(2.5.5, Method A\)](#)

Maximum 12.0.

[Saponification value \(2.5.6\)](#)

See Table 1618.-1.

Table 1618.-1

	5-6 moles of ethylene oxide	10 moles of ethylene oxide
Hydroxyl value	50 - 70	65 - 90
Iodine value	50 - 60	27 - 34
Saponification value	105 - 120	68 - 85

Composition of fatty acids

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

Composition of the fatty-acid fraction of the substance:

- [myristic acid](#): maximum 5.0 per cent;
- [stearic acid](#): maximum 6.0 per cent;
- [palmitic acid](#): maximum 16.0 per cent;
- [palmitoleic acid](#): maximum 8.0 per cent;
- [oleic acid](#): 65.0 per cent to 88.0 per cent;
- [linoleic acid](#): maximum 18.0 per cent;
- [linolenic acid](#): maximum 4.0 per cent;
- *fatty acids with a chain length greater than C_{18}* : maximum 4.0 per cent.

Residual ethylene oxide and dioxan ([2.4.25](#))

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

Water ([2.5.12](#))

Maximum 2.0 per cent, determined on 1.00 g using [anhydrous methanol R](#) as the solvent.

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 moles of ethylene oxide per mole (nominal value).

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