



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

Macrogol Glycerol Cocoates



[General Notices](#)

(*Macroglycerol Cocoates*, Ph. Eur. monograph 1122)

Action and use

Pharmaceutical aids.

Ph Eur

DEFINITION

Mixtures of mono-, di- and triesters of ethoxylated glycerol with fatty acids of vegetable origin having a composition corresponding to the fatty acid composition of the oil extracted from the hard, dried fraction of the endosperm of *Cocos nucifera* L. The average number of moles of ethylene oxide reacted per mole of substance (nominal value) is either 7 (macrogol 7 glycerol cocoate) or 23 (macrogol 23 glycerol cocoate).

CHARACTERS

Appearance

Clear, yellowish, oily liquid.

Solubility

Soluble in water and in ethanol (96 per cent) and practically insoluble in light petroleum (bp: 50-70 °C) for macrogol 7 glycerol cocoate and macrogol 23 glycerol cocoate.

[Relative density](#)

About 1.05 for macrogol 7 glycerol cocoate; about 1.09 for macrogol 23 glycerol cocoate.

IDENTIFICATION

A. Dissolve 1.0 g of macrogol 7 glycerol cocoate in 99 g of a mixture of 10 volumes of [2-propanol R](#) and 90 volumes of [water R](#). Heat the solution to about 65 °C. A turbidity is produced. Allow to cool until the turbidity disappears. The cloud point is between 35 °C and 54 °C.

Heat a 10 g/L solution of macrogol 23 glycerol cocoate in a 100 g/L solution of [sodium chloride R](#) to about 90 °C. A turbidity is produced. Allow to cool until the turbidity disappears. The cloud point is between 65 °C and 85 °C.

- B. Iodine value (see Tests).
- C. Saponification value (see Tests).

TESTS

Appearance

The substance to be examined is clear ([2.2.1](#)) and not more intensely coloured than reference solution Y₂ ([2.2.2, Method I](#)).

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 5.0, determined on 5.0 g.

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

See Table 1122.-1.

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

See Table 1122.-1.

Table 1122.-1

Number of moles of ethylene oxide reacted per mole (nominal value)	Hydroxyl value	Saponification value (determined on 2.0 g)
7	170 - 210	85 - 105
23	80 - 100	40 - 50

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

Maximum 5.0.

[Composition of fatty acids](#)

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

Composition of the fatty-acid fraction of the substance:

- [*caproic acid*](#): maximum 1.0 per cent;
- [*caprylic acid*](#): 5.0 per cent to 10.0 per cent;
- [*capric acid*](#): 4.0 per cent to 10.0 per cent;
- [*lauric acid*](#): 40.0 per cent to 55.0 per cent;
- [*myristic acid*](#): 14.0 per cent to 23.0 per cent;
- [*palmitic acid*](#): 8.0 per cent to 12.0 per cent;
- [*stearic acid*](#): 1.0 per cent to 5.0 per cent;
- [*oleic acid*](#): 5.0 per cent to 10.0 per cent;
- [*linoleic acid*](#): maximum 3.0 per cent.

Ethylene oxide and dioxan (2.4.25)

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

Water (2.5.12)

Maximum 1.0 per cent, determined on 1.0 g.

Total ash (2.4.16)

Maximum 0.3 per cent.

LABELLING

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

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