



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

Refined Maize Oil



[General Notices](#)

(*Ph. Eur. monograph 1342*)

Ph Eur

DEFINITION

Fatty oil obtained from the seeds of *Zea mays* L. by mechanical expression or by extraction. It is then refined.

PRODUCTION

The oil is prepared using materials and methods designed to ensure that the content of brassicasterol ([2.4.23](#)) in the sterol fraction of the oil is not greater than 0.3 per cent.

CHARACTERS

Appearance

Clear, light yellow or yellow oil.

Solubility

Practically insoluble in water and in ethanol (96 per cent), miscible with light petroleum (bp: 40-60 °C) and with methylene chloride.

[Relative density](#)

About 0.920.

[Refractive index](#)

About 1.474.

IDENTIFICATION

First identification: B.

Second identification: A.

A. Identification of fatty oils by thin-layer chromatography ([2.3.2](#)).

Results The chromatogram obtained with the test solution is similar to the chromatogram obtained with the reference solution.

B. Composition of fatty acids (see Tests).

TESTS

Acid value (2.5.1)

Maximum 0.5, or maximum 0.3 if intended for use in the manufacture of parenteral preparations, determined on 10.0 g.

Peroxide value (2.5.5, Method A)

Maximum 10.0, or maximum 5.0 if intended for use in the manufacture of parenteral preparations.

Unsaponifiable matter (2.5.7)

Maximum 2.8 per cent, determined on 5.0 g.

Alkaline impurities (2.4.19)

It complies with the test.

Composition of fatty acids (2.4.22, Method A)

Use the mixture of calibrating substances in Table 2.4.22.-3.

Composition of the fatty-acid fraction of the oil:

- *sum of fatty acids of chain length less than C_{16}* : maximum 0.6 per cent;
- *palmitic acid*: 8.6 per cent to 16.5 per cent;
- *stearic acid*: maximum 3.3 per cent;
- *oleic acid and isomer*: 20.0 per cent to 42.2 per cent;
- *linoleic acid*: 39.4 per cent to 65.6 per cent;
- *linolenic acid*: 0.5 per cent to 1.5 per cent;
- *arachidic acid*: maximum 0.8 per cent;
- *eicosenoic acid*: maximum 0.5 per cent;
- *behenic acid*: maximum 0.5 per cent;
- *any other fatty acid*: for each fatty acid, maximum 0.5 per cent.

Water (2.5.32)

Maximum 0.1 per cent, determined on 1.00 g.

STORAGE

Protected from light, at a temperature not exceeding 25 °C.

LABELLING

The label states:

- where applicable, that the substance is suitable for use in the manufacture of parenteral preparations;
- whether the oil is obtained by mechanical expression or by extraction.

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