



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

Refined Soya Oil



[General Notices](#)

Refined Soyabean Oil

(*Refined Soya-bean Oil*, Ph. Eur. monograph 1473)

Action and use

Excipient.

When Soya Oil, Soyabean Oil or Soya-bean Oil is demanded, Refined Soya Oil shall be supplied.

When intended for use in the manufacture of a parenteral dosage form, Refined Soya Oil complying with the requirement for Water below should be used.

Ph Eur

DEFINITION

Fatty oil obtained from seeds of *Glycine max* (L.) Merr. (*Glycine hispida* (Moench) Maxim.) by extraction and subsequent refining. It may contain a suitable antioxidant.

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, pale yellow liquid.

Solubility

Practically insoluble in ethanol (96 per cent), miscible with light petroleum (bp: 50-70 °C).

[Relative density](#)

About 0.922.

[Refractive index](#)

About 1.475.

IDENTIFICATION

First identification: B.

Second identification: A.

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

Results The chromatogram obtained is similar to the corresponding chromatogram shown in Figure 2.3.2.-1.

B. Composition of fatty acids (see Tests).

TESTS

Acid value ([2.5.1](#))

Maximum 0.5.

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 1.5 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:

- *saturated fatty acids of chain length less than C_{14}* : maximum 0.1 per cent;
- *myristic acid*: maximum 0.2 per cent;
- *palmitic acid*: 9.0 per cent to 13.0 per cent;
- *palmitoleic acid*: maximum 0.3 per cent;
- *stearic acid*: 2.0 per cent to 5.4 per cent;
- *oleic acid and isomer*: 17.0 per cent to 30.0 per cent;
- *linoleic acid*: 48.0 per cent to 58.0 per cent;
- *linolenic acid*: 4.5 per cent to 11.0 per cent;
- *arachidic acid*: maximum 1.0 per cent;
- *eicosenoic acid*: maximum 1.0 per cent;
- *behenic acid*: maximum 1.0 per cent.

Water ([2.5.32](#))

Maximum 0.1 per cent, determined on 1.00 g.

STORAGE

In a well-filled container, protected from light, at a temperature not exceeding 25 °C. If intended for use in the manufacture of parenteral preparations, store under an inert gas.

LABELLING

The label states, where applicable, that the substance is suitable for use in the manufacture of parenteral preparations and the name of the inert gas.

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