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

Sorbitan Trioleate

General Notices

(Ph. Eur. monograph 1044)

Action and use

Non-ionic surfactant.

Ph Eur

DEFINITION

Mixture usually obtained by esterification of 1 mole of sorbitol and its mono-anhydride per 3 moles of oleic ((9*Z*)-octadec-9-enoic) acid. A suitable antioxidant may be added.

CHARACTERS

Appearance

Pale yellow, light yellowish or brown solid, which becomes a viscous, oily, brownish-yellow liquid at about 25 °C.

Solubility

Practically insoluble but dispersible in water, soluble in fatty oils, slightly soluble in ethanol (96 per cent).

Relative density

About 0.98.

IDENTIFICATION

A. Hydroxyl value (see Tests).
B. Iodine value (see Tests).
C. Composition of fatty acids (see Tests).

Margaric acid Maximum 0.2 per cent for oleic acid of vegetable origin and maximum 4.0 per cent for oleic acid of animal origin.

TESTS

Acid value (*2.5.1*)

Maximum 16.0, determined on 5.0 g.

Hydroxyl value (*2.5.3, Method A*)

55 to 75.

Iodine value (*2.5.4*)

76 to 90.

Peroxide value (*2.5.5*)

Maximum 10.0.

Saponification value (*2.5.6*)

170 to 190.

Carry out the saponification for 1 h.

Composition of fatty acids

Gas chromatography (*2.4.22, Method C*).

Composition of the fatty acid fraction of the substance:

— *myristic acid*: maximum 5.0 per cent;

— *palmitic acid*: maximum 16.0 per cent;

— *palmitoleic acid*: maximum 8.0 per cent;

— *stearic acid*: maximum 6.0 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 chain length greater than* C_{18}: maximum 4.0 per cent.

Water (*2.5.12*)

Maximum 1.5 per cent, determined on 1.00 g.

Total ash (*2.4.16*)

Maximum 0.5 per cent, determined on 1.5 g.

STORAGE

Protected from light.

LABELLING

The label states the origin of the oleic acid used (animal or vegetable).

FUNCTIONALITY-RELATED CHARACTERISTICS

This section provides information on characteristics that are recognised as being relevant control parameters for one or more functions of the substance when used as an excipient (see chapter 5.15). Some of the characteristics described in the Functionality-related characteristics section may also be present in the mandatory part of the monograph since they also represent mandatory quality criteria. In such cases, a cross-reference to the tests described in the mandatory part is included in the Functionality-related characteristics section. Control of the characteristics can contribute to the quality of a medicinal product by improving the consistency of the manufacturing process and the performance of the medicinal product during use. Where control methods are cited, they are recognised as being suitable for the purpose, but other methods can also be used. Wherever results for a particular characteristic are reported, the control method must be indicated.

The following characteristics may be relevant for sorbitan trioleate used as emulsifier and co-solubiliser in creams.

Composition of fatty acids

(see Tests).

Hydroxyl value

(see Tests).

Ph Eur