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

Macrogol 40 Sorbitol Heptaoleate

General Notices

(Ph. Eur. monograph 2396)

Action and use

Non-ionic surfactant.

Ph Eur

DEFINITION

Mixture of esters of fatty acids, mainly *Oleic acid (0799)*, and sorbitol ethoxylated with approximately 40 moles of ethylene oxide for each mole of sorbitol. 7 moles of oleic acid are used for each mole of sorbitol. It also contains macrogol fatty acid esters.

CHARACTERS

Appearance

Clear or slightly opalescent, yellowish, viscous, hygroscopic liquid.

Solubility

Dispersible in water, soluble in isopropyl myristate, in isopropyl palmitate, in mineral oils and in vegetable fatty oils.

Relative density

About 1.0.

Viscosity (*2.2.9*): about 175 mPa·s at 25 °C.

IDENTIFICATION

First identification: A, D.

Second identification: B, C, D.

A. Infrared absorption spectrophotometry (2.2.24).

Comparison *macrogol 40 sorbitol heptaoleate CRS*.

B. Hydroxyl value (see Tests).
C. Saponification value (see Tests).
D. Composition of fatty acids (see Tests).

TESTS

Acid value (*2.5.1*)

Maximum 12.0, determined on 3.0 g.

Hydroxyl value (*2.5.3, Method A*)

22 to 55.

Peroxide value

Maximum 10.0.

Introduce 10.0 g into a 100 mL beaker and dissolve with 20 mL of *glacial acetic acid R*. Add 1 mL of *saturated potassium iodide solution R*, mix and allow to stand for 1 min. Add 50 mL of *carbon dioxide-free water R* and a magnetic stirring bar. Titrate with *0.01 M sodium thiosulfate*, determining the end-point potentiometrically (*2.2.20*). Carry out a blank titration.

Determine the peroxide value using the following expression:

$$\frac{(n_1 - n_2) \times M \times 1000}{m}$$

n_1	=	volume of *0.01 M sodium thiosulfate* required for the titration of the substance to be examined, in millilitres;
n_2	=	volume of *0.01 M sodium thiosulfate* required for the blank titration, in millilitres;
M	=	molarity of the sodium thiosulfate solution;
m	=	mass of the substance to be examined, in grams.

Saponification value (*2.5.6*)

90 to 110, determined on 4.0 g.

Use 30.0 mL of 0.5 M alcoholic potassium hydroxide, heat under reflux for 60 min and add 50 mL of *anhydrous ethanol R* before carrying out the titration.

Composition of fatty acids (*2.4.22, Method C*)

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

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*: minimum 58.0 per cent;

— *linoleic acid*: maximum 18.0 per cent;

— *linolenic acid*: maximum 4.0 per cent.

Ethylene oxide and dioxan (*2.4.25, Method A*)

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

Water (*2.5.12*)

Maximum 0.5 per cent, determined on 0.50 g.

Sulfated ash

Maximum 0.25 per cent.

Heat a silica crucible to redness for 30 min, allow to cool in a desiccator and weigh. Evenly distribute 1.0 g of the substance to be examined in the crucible and weigh. Dry at 100-105 °C for 1 h and ignite in a muffle furnace at 600 ± 25 °C, until the substance is thoroughly charred. Carry out the test for sulfated ash (*2.4.14*) on the residue obtained, starting from “Moisten the substance to be examined...”.

STORAGE

In an airtight container, protected from light.

Ph Eur