

**Water** (2.5.12): maximum 3.0 per cent, determined on 1.00 g.

**Total ash** (2.4.16): maximum 0.2 per cent, determined on 1.0 g.

#### STORAGE

Protected from light.

#### LABELLING

The label states the type of macrogol 20 glycerol monostearate.

01/2005:1123

## MACROGOL CETOSTEARYL ETHER

### Macrogoli aether cetostearylicus

#### DEFINITION

Macrogol cetostearyl ether is a mixture of ethers of mixed macrogols with linear fatty alcohols, mainly cetostearyl alcohol. It may contain some free macrogols and it contains various amounts of free cetostearyl alcohol. The amount of ethylene oxide reacted with cetostearyl alcohol is from 2 to 33 units per molecule (nominal value).

#### CHARACTERS

A waxy, white or yellowish-white, unctuous mass, pellets, microbeads or flakes.

Macrogol cetostearyl ether with low numbers of ethylene oxide units per molecule is practically insoluble in water, soluble in alcohol and in methylene chloride.

Macrogol cetostearyl ether with higher numbers of ethylene oxide units per molecule is dispersible or soluble in water, soluble in alcohol and in methylene chloride.

It solidifies at 32 °C to 52 °C.

#### IDENTIFICATION

- It complies with the test for hydroxyl value (see Tests).
- It complies with the test for iodine value (see Tests).
- It complies with the test for saponification value (see Tests).
- Examine by thin-layer chromatography (2.2.27), using a suitable silica gel as the coating substance.

**Test solution.** Dissolve the amount of substance to be examined (given in Table 1123.-1) in a mixture of 1 volume of *water R* and 9 volumes of *methanol R* and dilute to 75 ml with the same mixture of solvents.

Table 1123.-1

Ethylene oxide units per molecule	Amount to be dissolved
2 - 6	5.0 g
10 - 22	10.0 g
25 - 33	15.0 g

Add 60 ml of *hexane R* and shake for 3 min. The formation of foam can be reduced by the addition of some drops of *alcohol R*. Pass the hexane layer through a filter with *anhydrous sodium sulphate R*, wash the filter with 3 quantities, each of 10 ml, of *hexane R* and evaporate the combined filtrates to dryness. Dissolve 0.05 g of the residue in 10 ml of *methanol R* (sometimes the solution is opalescent).

**Reference solution.** Dissolve 25 mg of *stearyl alcohol CRS* in *methanol R* and dilute to 25 ml with the same solvent.

Apply separately to the plate 20 µl of each solution. Develop over a path of 15 cm using *ethyl acetate R*. Dry and spray with vanillin-sulphuric acid reagent prepared as follows: dissolve 0.50 g of *vanillin R* in 50.0 ml of *alcohol R* and dilute to 100.0 ml with *sulphuric acid R*. Allow the plate to dry in air. Heat the plate at about 130 °C for 15 min and allow to cool in air. The chromatogram obtained with the test solution shows several spots; one of these spots corresponds to the principal spot in the chromatogram obtained with the reference solution.

- Dissolve or disperse 0.1 g in 5 ml of *alcohol R*, add 2 ml of *water R*, 10 ml of *dilute hydrochloric acid R*, 10 ml of *barium chloride solution R1* and 10 ml of a 100 g/l solution of *phosphomolybdic acid R*. A precipitate is formed.

#### TESTS

**Appearance of solution.** Dissolve 5.0 g in *alcohol R* and dilute to 50 ml with the same solvent. The solution is not more intensely coloured than reference solution BY<sub>5</sub> (2.2.2, Method II).

**Alkalinity.** Dissolve 2.0 g in a hot mixture of 10 ml of *water R* and 10 ml of *alcohol 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). Not more than 1.0, determined on 5.0 g.

**Hydroxyl value** (2.5.3, Method A).

Ethylene oxide units per molecule (nominal value)	Hydroxyl value
2	150 - 180
3	135 - 155
5 - 6	100 - 134
10	75 - 90
12	67 - 77
15	58 - 67
20 - 22	40 - 55
25	36 - 46
30 - 33	32 - 40

**Iodine value** (2.5.4). Not more than 2.0.

**Saponification value** (2.5.6). Not more than 3.0, determined on 10.0 g.

**Ethylene oxide and dioxan** (2.4.25). Not more than 1 ppm of ethylene oxide and not more than 10 ppm of dioxan.

**Water** (2.5.12). Not more than 3.0 per cent, determined on 2.00 g by the semi-micro determination of water.

**Total ash** (2.4.16). Not more than 0.2 per cent, determined on 2.0 g.

#### STORAGE

Store in an airtight container.

#### LABELLING

The label states the amount of ethylene oxide reacted with cetostearyl alcohol (nominal value).