Macrogolglycerol hydroxystearate

DEFINITION
Contains mainly trihydroxystearyl glycerol ethoxylated with 7 to 60 molecules of ethylene oxide (nominal value), with small amounts of macrogol hydroxystearate and of the corresponding free glycols. It results from the reaction of hydrogenated castor oil with ethylene oxide.

CHARACTERS
Appearance:
- if less than 10 units of ethylene oxide per molecule: yellowish, turbid, viscous liquid; if more than 20 units of ethylene oxide per molecule: white or yellowish semi-liquid or pasty mass.

Solubility:
- if less than 10 units of ethylene oxide per molecule: practically insoluble in water, soluble in acetone, dispersible in ethanol (96 per cent); if more than 20 units of ethylene oxide per molecule: freely soluble in water, in acetone and in ethanol (96 per cent), practically insoluble in light petroleum.

IDENTIFICATION
A. It complies with the test for iodine value (see Tests).
B. It complies with the test for saponification value (see Tests).
C. Thin-layer chromatography (2.2.27).

Test solution. To 1 g of the substance to be examined, add 100 ml of a 100 g/l solution of potassium hydroxide R and boil under a reflux condenser for 30 min. Allow to cool. Acidify the solution with 20 ml of hydrochloric acid R. Shake the mixture with 50 ml of ether R and allow to stand until separation of the layers is obtained. Transfer the clear upper layer to a suitable tube, add 5 g of anhydrous sodium sulphate R, close the tube and allow to stand for 30 min. Filter and evaporate the filtrate to dryness on a water-bath. Dissolve 50 mg of the residue in 25 ml of ether R.

Reference solution. Dissolve 50 mg of 12-hydroxystearic acid R in methylene chloride R and dilute to 25 ml with the same solvent.

Plate: TLC octadecleryl silica gel plate R.
Application: 2 μl.
Development: over a path of 8 cm.
Drying: in a current of cold air.

Detection: spray with a 80 g/l solution of phosphomolybdic acid R in 2-propanol R and heat at 120 °C for about 1-2 min.

Results: the principal spot in the chromatogram obtained with the test solution is similar in position and colour to the principal spot in the chromatogram obtained with the reference solution.

D. Place about 2 g in a test-tube and add 0.2 ml of sulphuric acid R. Close the tube using a stopper fitted with a glass tube bent twice at right angles. Heat the tube until white fumes appear. Collect the fumes in 1 ml of mercuric chloride solution R. A white precipitate is formed and the fumes turn a filter paper impregnated with alkaline potassium tetraiodomercurate solution R black.

TESTS
Solution S. Dissolve 5.0 g of macrogolglycerol hydroxystearate with less than 40 units of ethylene oxide per molecule in a mixture of 50 volumes of acetone R and 50 volumes of anhydrous ethanol R and dilute to 50 ml with the same mixture of solvents.

Dissolve 5.0 g of macrogolglycerol hydroxystearate with 40 units or more of ethylene oxide per molecule in carbon dioxide-free water R and dilute to 50 ml with the same solvent.

Appearance of solution. Solution S is not more opalescent than reference suspension III (2.2.1) and not more intensely coloured than reference solution BY9 (2.2.2, Method II).

Alkalinity. To 2 ml of solution S add 0.5 ml of bromothymol blue solution R1. The solution is not blue.

Acid value (2.5.1): maximum 2.0, determined on 5.0 g.

Hydroxyl value (2.5.3, Method A). See Table 1083-1.

Iodine value (2.5.4): maximum 5.0.

Saponification value (2.5.6). See Table 1083-1.

<table>
<thead>
<tr>
<th>Table 1083-1</th>
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<tbody>
<tr>
<td>Ethylene oxide units per molecule (nominal value)</td>
</tr>
<tr>
<td>7</td>
</tr>
<tr>
<td>25</td>
</tr>
<tr>
<td>40</td>
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<tr>
<td>60</td>
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</tbody>
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Residual ethylene oxide and dioxan (2.4.25): maximum 1 ppm of residual ethylene oxide and 10 ppm of residual dioxan.

Heavy metals (2.4.8).
Substances soluble in acetone/anhydrous ethanol: maximum 10 ppm.
12 ml of solution S complies with limit test B. Prepare the reference solution using lead standard solution (1 ppm Pb) obtained by diluting lead standard solution (100 ppm Pb) R with a mixture of equal volumes of acetone R and anhydrous ethanol R.

Substances soluble in water: maximum 10 ppm.
12 ml of solution S complies with limit test A. Prepare the reference solution using lead standard solution (1 ppm Pb) R.

General Notices (1) apply to all monographs and other texts
Macrogol 20 glycerol monostearate

**DEFINITION**

Macrogol 20 glycerol monostearate is obtained by ethoxylation with ethylene oxide of different types of glycerol stearates, mainly Glycerol monostearate 40-55 (0495). The number of moles of ethylene oxide reacted per mole of glycerol stearate is 20 (nominal value).

**CHARACTERS**

*Appearance*: pale yellow, oily liquid or gel.

*Solubility*: soluble in water at 40 °C and above and in ethanol (96 per cent), practically insoluble in light liquid paraffin and in fatty oils.

*Relative density*: about 1.07.

**IDENTIFICATION**

A. Hydroxyl value (see Tests).

B. Saponification value (see Tests).

C. Composition of fatty acids (see Tests).

D. Place 1 g in a test tube and add 0.1 ml of sulphuric acid R. Heat the tube until white fumes appear. The fumes turn filter paper impregnated with alkaline potassium tetratiodomercurate solution R black.

**TESTS**

*Acid value* (2.5.1): maximum 2.0, determined on 5.0 g.

*Hydroxyl value* (2.5.3, Method A): 65 to 85, determined on 0.350 g.

*Iodine value* (2.5.4, Method A): maximum 2.0.

*Peroxide value* (2.5.5, Method A): maximum 6.0.

*Saponification value* (2.5.6): 40 to 60.

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**MACROGOL 20 GLYCEROL MONOSTEARATE**

Macrogol 20 glyceroli monostearas

**DEFINITION**

Macrogol 20 glycerol monostearate is obtained by ethoxylation with ethylene oxide of different types of glycerol stearates, mainly Glycerol monostearate 40-55 (0495). The number of moles of ethylene oxide reacted per mole of glycerol stearate is 20 (nominal value).

**CHARACTERS**

*Appearance*: pale yellow, oily liquid or gel.

*Solubility*: soluble in water at 40 °C and above and in ethanol (96 per cent), practically insoluble in light liquid paraffin and in fatty oils.

*Relative density*: about 1.07.

**IDENTIFICATION**

A. Hydroxyl value (see Tests).

B. Saponification value (see Tests).

C. Composition of fatty acids (see Tests).

D. Place 1 g in a test tube and add 0.1 ml of sulphuric acid R. Heat the tube until white fumes appear. The fumes turn filter paper impregnated with alkaline potassium tetratiodomercurate solution R black.

**TESTS**

*Acid value* (2.5.1): maximum 2.0, determined on 5.0 g.

*Hydroxyl value* (2.5.3, Method A): 65 to 85, determined on 0.350 g.

*Iodine value* (2.5.4, Method A): maximum 2.0.

*Peroxide value* (2.5.5, Method A): maximum 6.0.

*Saponification value* (2.5.6): 40 to 60.

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**MACROGOLGLYCEROL RICINOLEATE**

Macrogolglyceroli ricinoleas

**DEFINITION**

Contains mainly ricinoleyl glycerol ethoxylated with 30-50 molecules of ethylene oxide (nominal value), with small amounts of macrogol ricinoleate and of the corresponding free glycols. It results from the reaction of castor oil with ethylene oxide.

**CHARACTERS**

*Appearance*: clear, yellow viscous liquid or semi-solid.

*Solubility*: freely soluble in water, very soluble in methylene chloride, freely soluble in ethanol (96 per cent).

*Relative density*: about 1.05.

*Viscosity*: 500 mPas to 800 mPas at 25 °C.

**IDENTIFICATION**

A. Iodine value (see Tests).

B. Saponification value (see Tests).

C. Thin-layer chromatography (2.2.27).

**TESTS**

*Test solution*. To 1 g of the substance to be examined add 100 ml of a 100 g/l solution of potassium hydroxide R and boil under a reflux condenser for 30 min. Allow to cool. Acidify the solution with 20 ml of hydrochloric acid R. Shake the mixture with 50 ml of ether R and