Glyceryl monostearate (Glyceroli monostearas)

$C_{21}H_{42}O_4$

Chemical name. Monostearin; ocatadecanoic acid monoester with 1,2,3-propanetriol; CAS Reg. No. 31566-31-1.

Description. A white or yellowish white, hard waxy mass or unctuous powder or flakes; odourless or slight, agreeable, fatty odour.

Solubility. Practically insoluble in water; soluble in ether R, benzene R, and ethanol (~750 g/l) TS at 60 °C.

Category. Emulsifying agent; cream and ointment base.

Storage. Glyceryl monostearate should be kept in a tightly closed container, protected from light.

Additional information. Glyceryl monostearate may contain a suitable antioxidant. Self-emulsifying glyceryl monostearate contains additional emulsifying agents.

Requirements

Definition. Glyceryl monostearate is a mixture of mono-, di- and triglycerides of stearic and palmitic acids.

Glyceryl monostearate contains not less than the equivalent of **35.0%** of monoglycerides, calculated as $C_{20}H_{40}O_4$, and not more than the equivalent of **6.0%** of free glycerol.

Identity tests

A. Melting temperature, not lower than 55 °C.

B. Dip a strip of filter-paper in a freshly prepared solution containing 9.5 mL of sodium nitroprusside (8.5 g/l) TS and 0.5 mL of piperidine R. Place the moistened filter-paper into the evolving vapours over the mouth of the test-tube containing 1 g of Glyceryl monostearate and heat with 2 mL of phosphoric acid (~1440 g/l) TS; a deep blue colour develops on the paper.

C. Heat 2.5 g with 40 mL of potassium hydroxide/ethanol TS1 on a water-bath under reflux for 30 minutes. Add 30 mL of water, evaporate the ethanol, acidify the hot mixture with 15 mL of hydrochloric acid (~70 g/l) TS, cool, and shake with 50 mL of ether R. Wash the ether layer with three quantities, each of a mixture of 5 mL of sodium chloride (400 g/l) TS and 5 mL of water, dry the ether layer over anhydrous sodium sulfate R, and filter. Evaporate the filtrate and dry the residue under reduced pressure at room temperature. Melt the residue, introduce it into capillary tubes, and keep the tubes for 24 hours in a well-closed container. Melting temperature, not lower than 53 °C.

Acid value. Not more than 6.0.

Saponification value. 155-177.

Iodine value. Not more than 3.

Sulfated ash. Not more than 1.0 mg/g.

Assays. Transfer about 0.4 g, accurately weighed, to a glass-stoppered separating funnel, and dissolve in 50 mL of dichloromethane R. Add 25 mL of water and shake vigorously for 1 minute. Allow the layers to separate. If an emulsion is formed, add a few drops of glacial acetic acid R. Carry out the extraction three more times using 25 mL, 20 mL, and 20 mL of water. Combine the dichloromethane extracts and use them in the assay for *monoglycerides*. Filter the aqueous layers through a filter-paper moistened with water, wash the filter with two quantities, each of 5 mL, of water, and dilute the combined filtrates and wash liquids to 100 mL with water. Use this solution for the assay for *free glycerol*.

Free glycerol

Place 50 mL of the prepared aqueous solution in a 500-mL ground-glass-stoppered conical flask, add 25 mL of periodic-acetic acid TS, and shake cautiously. Allow to stand at a temperature between 25 and 30 °C for 30 minutes. Add 100 mL of water and 25 mL of potassium iodide (80 g/l) TS. Titrate with sodium thiosulfate (0.1 mol/l) VS, using 1 mL of starch TS as indicator added towards the end of the titration. Repeat the procedure without the Glyceryl monostearate being examined and make any necessary corrections.

Each mL of sodium thiosulfate (0.1 mol/l) VS is equivalent to 2.3 mg of glycerol.

Monoglycerides

Filter the combined dichloromethane extracts through a plug of cotton-wool. Wash the separating funnel and the filter with three quantities, each of 5 mL, of dichloromethane R, and dilute the filtrate to 100 mL with dichloromethane R. Carry out the assay as described for free glycerol, using 50 mL of the dichloromethane solution.

Each mL of sodium thiosulfate (0.1 mol/l) VS is equivalent to 17.2 mg of monoglycerides, calculated as $C_{20}H_{40}O_4$.