

**Hard fat (Adeps solidus)**

**Chemical name.** Hard fat.

**Description.** A white, brittle, unctuous mass; almost odourless.

**Solubility.** Practically insoluble in water; freely soluble in ether R; slightly soluble in ethanol (~750 g/l) TS.

**Category.** Suppository base.

**Storage.** Hard fat should be kept in a well-closed container, protected from light, and stored at a temperature not exceeding 5 °C below the melting range.

**Additional information.** On warming, hard fat melts to a colourless to slightly yellow liquid. On shaking the molten material with an equal quantity of hot water, forms a white emulsion.

*Note:* For certain applications, it may be necessary to comply with more restrictive specifications.

**Requirements**

**Definition.** Hard fat is a mixture of mono-, di- and triglyceride esters of higher saturated fatty acids ( $C_{10}H_{20}O_2$  to  $C_{18}H_{36}O_2$ ).

**Melting range.** Cool the charged tube at a temperature below 10 °C for 24 hours; 33-40 °C.

**Acid value.** Not more than 0.5.

**Hydroxyl value.** Not more than 50.

**Iodine value.** Not more than 3.

**Peroxide value.** Not more than 6.

**Saponification value.** Use 2.0 g; 220-250.

**Unsaponifiable matter.** Use 5 g; not more than 1.0%.

**Ash.** Not more than 0.5 mg/g.

**Alkaline impurities.** Dissolve 2 g in a mixture of 1.5 mL of ethanol (~750 g/l) TS and 3 mL of ether R. Add 0.05 mL of bromophenol blue/ethanol TS; not more than 0.15 mL of hydrochloric acid (0.01 mol/l) VS is required to change the colour of the solution to yellow.

**Decomposition products.** Shake 1 g with 1 mL of hydrochloric acid (~420 g/l) TS for 1 minute, add 1 mL of resorcinol/toluene TS, shake for 5 seconds, and allow to stand for 5 minutes; the aqueous layer is not more intensely coloured than 1 mL of a mixture of 0.4 mL of potassium permanganate (0.002 mol/l) VS and 9.6 mL of water.