POLYOXYETHYLENE (20) SORBITAN MONOSTEARATE

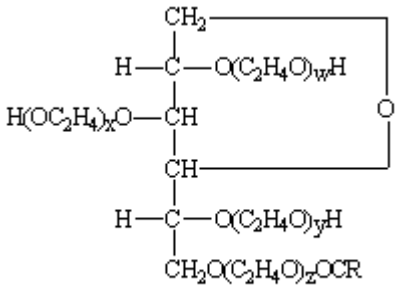
Revised specifications prepared at the 79th JECFA (2014) published in FAO JECFA Monographs 16 (2014) superseding specifications prepared at the 25th JECFA (1981), published in FNP 19 (1981) and in FNP 52 (1992). Metals and arsenic specifications revised at the 55th JECFA (2000). An ADI of 0-25 mg/kg bw was established at the 17th JECFA (1973).

SYNONYMS Polysorbate 60; INS No. 435

DEFINITION Polyoxyethylene (20) sorbitan monostearate consists of a mixture of the partial esters of sorbitol and its mono- and dianhydrides (which have an acid value below 10 and a water content below 0.2%) with the food-grade stearic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides.

C.A.S. number 9005-07-6

Structural formula Nominal formula and approximate composition:



where w + x + y + z = approx. 20 and RCO- is the fatty acid moiety

Assay Not less than 65.0 and not more than 69.5% of oxyethylene groups, equivalent to not less than 97.0 and not more than 103.0% of polyoxyethylene (20) sorbitan monostearate, on the anhydrous basis

DESCRIPTION Yellow to orange coloured oily liquid or semi-gel at 25°, with a faint characteristic odour

FUNCTIONAL USES Emulsifier, dispersing agent

CHARACTERISTICS

IDENTIFICATION

Solubility (Vol. 4) Soluble in water, ethyl acetate and toluene; insoluble in mineral oil and vegetable oils

Infrared absorption The infrared spectrum of the sample is characteristic of a partial fatty acid ester of a polyoxyethylated polyol

Colour reaction To 5 ml of a 5% (w/v) aqueous solution of the sample add 10 ml of ammonium cobaltothiocyanate solution and 5 ml of chloroform, shake well

	and allow to separate; a blue colour is produced in the chloroform layer. (Ammonium cobaltothiocyanate solution: 37.5 g of cobalt nitrate and 150 g of ammonium thiocyanate made up to 100 ml with water - freshly prepared).
Test for fatty acids	To 5 ml of a 5% (w/v) aqueous solution of the sample add 5 ml sodium hydroxide TS. Boil for a few min, cool, and acidify with dilute hydrochloric acid. The solution is strongly opalescent, owing to the fatty acids liberated.
Gelatinization	A mixture of 60 parts by volume of the sample and 40 parts of water yields a gelatinous mass at or below room temperature
Saponification (Vol. 4)	100 g of the sample yields approximately 25 g of fatty acids and 77 g of polyols
PURITY	
Water (Vol. 4)	Not more than 3% (Karl Fischer Method)
Sulfated ash (Vol. 4)	Not more than 0.25% Test 5 g of the sample
Acid value (Vol. 4)	Not more than 2
Saponification value (Vol. 4)	Not less than 45 and not more than 55
Hydroxyl value (Vol. 4)	Not less than 81 and not more than 96
1,4-Dioxane (Vol. 4)	Not more than 10 mg/kg
Lead (Vol. 4)	Not more than 2 mg/kg Determine using an AAS (Electrothermal atomization technique) appropriate to the specified level. The selection of sample size and method of sample preparation may be based on principles of methods described in Volume 4 (under “General Methods, Metallic Impurities”)
METHOD OF ASSAY	Determine the content of *Oxyethylene groups* (Vol. 4)