POLYOXYETHYLENE (20) SORBITAN TRISTEARATE


SYNONYMS
Polysorbate 65; INS No. 436

DEFINITION
Consists of a mixture of the partial esters of sorbitol and its mono- and dianhydrides (which have an acid value below 15 and a water content below 0.2%) with edible commercial stearic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides.

Structural formula
Nominal formula and approximate composition:

\[
\begin{align*}
\text{CH}_2 & \quad \text{H-C-O(C}_2\text{H}_4\text{O)}\text{yH} \\
\text{H(OCH}_2\text{CH}_2\text{O)}\text{xO} & \quad \text{CH} \\
\text{H-C-O(C}_2\text{H}_4\text{O)}\text{yH} & \quad \text{CH}_2\text{O(C}_2\text{H}_4\text{O)}\text{zOCR}
\end{align*}
\]

where \( w + x + y + z \approx \text{approx. 20} \) and \( \text{RCO-} \) is the fatty acid moiety

Assay
Not less than 46.0 and not more than 50.0% of oxyethylene groups, equivalent to not less than 96.0 and not more than 104.0% of polyoxyethylene (20) sorbitan tristearate on the anhydrous basis

DESCRIPTION
Tan coloured, waxy solid at 25\(^\circ\), with a faint characteristic odour

FUNCTIONAL USES
Emulsifier, dispersing agent

CHARACTERISTICS
IDENTIFICATION
Solubility (Vol. 4)
Dispersible in water; soluble in mineral oil, vegetable oils, petroleum ether, acetone, ether, dioxane, ethanol and methanol

Congealing range (Vol. 4)
29 - 33\(^\circ\)

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 cobalt thiocyanate solution and 5 ml of chloroform, shake well and allow to separate; a blue colour is produced in the chloroform layer.

(Ammonium cobalt thiocyanate 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.

**Saponification (Vol. 4)**
100 g of the sample yields approximately 43 g of fatty acids and 56 g of polyols

**PURITY**

**Water (Vol. 4)**
Not more than 3% (Karl Fischer Method)

**Sulfated ash (Vol. 4)**
Not more than 0.25%
Test 2 g of the sample (Method I)

**Acid value (Vol. 4)**
Not more than 2

**Saponification value (Vol. 4)**
Not less than 88 and not more than 98

**Hydroxyl value (Vol. 4)**
Not less than 40 and not more than 60

**1,4-Dioxane (Vol. 4)**
Not more than 10 mg/kg

**Lead (Vol. 4)**
Not more than 2 mg/kg
Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in Volume 4, “Instrumental Methods.”

**METHOD OF ASSAY**
Determine the content of Oxyethylene groups.