

Polysorbate 65

Polyoxyethylene (20) Sorbitan Tristearate

CAS: 9005-71-4

DESCRIPTION

Polysorbate 65 is a mixture of stearate and palmitate partial esters of sorbitol and its anhydrides condensed with approximately 20 moles of ethylene oxide (C₂H₄O) for each mole of sorbitol and its mono- and dianhydrides. It is a tan, waxy solid having a faint, characteristic odor and a warm, somewhat bitter taste. It is soluble in mineral oil and in vegetable oils, mineral

spirits, acetone, ether, dioxane, alcohol, and methanol, and it is dispersible in water.

Functional Use in Foods Emulsifier; stabilizer.

REQUIREMENTS

Identification To 5 mL of a 1 in 20 solution add 5 mL of 1 *N* sodium hydroxide, boil for a few min, cool, and acidify with 2.7 *N* hydrochloric acid. The solution is strongly opalescent.

Assay for Oxyethylene Content Not less than 46.0% and not more than 50.0% of oxyethylene groups ($-\text{C}_2\text{H}_4\text{O}-$), equivalent to between 96.0% and 104.0% of Polysorbate 65, calculated on the anhydrous basis.

Acid Value Not more than 2.

1,4-Dioxane Not more than 10 mg/kg.

Heavy Metals (as Pb) Not more than 10 mg/kg.

Hydroxyl Value Between 44 and 60.

Residue on Ignition Not more than 0.25%.

Saponification Value Between 88 and 98.

Stearic and Palmitic Acids Between 42 and 44 g/100 g of sample.

Water Not more than 3.0%.

TESTS

Assay for Oxyethylene Content Weigh accurately a 90-mg sample, and proceed as directed in the general method, Appendix VII.

Acid Value Determine as directed for *Acid Value, Method II*, under *Fats and Related Substances*, Appendix VII.

1,4-Dioxane Determine as directed under *1,4-Dioxane* in the monograph for *Polysorbate 20*.

Heavy Metals Prepare and test a 2-g sample as directed in *Method II* under the *Heavy Metals Test*, Appendix IIIB, using 20 μg of lead ion (Pb) in the control (*Solution A*).

Hydroxyl Value Determine as directed under *Method II* in the general method, Appendix VII.

Residue on Ignition Ignite 5 g as directed in the general method, Appendix IIC.

Saponification Value Determine as directed in the general method, Appendix VII, using about 6 g, accurately weighed.

Stearic and Palmitic Acids Isolate the fatty acids as directed under *Lauric Acid* in the monograph for *Polysorbate 20*, and determine the weight of the acids. The product so obtained has an *Acid Value* between 200 and 212 (*Method I*, Appendix VII) and a *Solidification Point*, Appendix IIB, not below 52°.

Water Determine by the *Karl Fischer Titrimetric Method*, Appendix IIB.

Packaging and Storage Store in tight containers.