Polysorbate 20

Polyoxyethylene (20) Sorbitan Monolaurate; Sorbitan, Monododecanoate; Poly(oxy-1,2-ethanediyl) Derivative

CAS: [9005-64-5]

DESCRIPTION

Polysorbate 20 is a mixture of laurate partial esters of sorbitol and sorbitol anhydrides condensed with approximately 20 moles of ethylene oxide (C_2H_4O) for each mole of sorbitol and its mono- and dianhydrides. It is a lemon- to amber-colored liquid having a faint, characteristic odor and a warm, somewhat bitter taste. It is soluble in water, in alcohol, in ethyl acetate, in methanol, and in dioxane, but is insoluble in mineral oil and in mineral spirits.

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 70.0% and not more than 74.0% of oxyethylene groups ($—C_2H_4O—$), equivalent to between 97.3% and 103.0% of Polysorbate 20, 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 96 and 108.
Lauric Acid Between 15 and 17 g/100 g of sample.
Residue on Ignition Not more than 0.25%.
Saponification Value Between 40 and 50.
Water Not more than 3.0%.

TESTS

Assay for Oxyethylene Content Weigh accurately a 65-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

Stripped Polysorbate Prepare an appropriate quantity of 1,4-dioxane-free Polysorbate 20 by stripping it at 10 mm of mercury, with nitrogen sparge at 130° for 4 h or until, when tested as directed under *Procedure*, no 1,4-dioxane is detected.

1,4-Dioxane Standard Preparation By appropriate quantitative dilutions using *Stripped Polysorbate*, prepare a standard preparation containing 10 µg/mL of 1,4-dioxane. Transfer 5.0 g, accurately weighed, of the *1,4-Dioxane Standard Preparation* to a 22-mL pressure headspace vial; seal with a silicone septum, star spring, and pressure-relief safety aluminum sealing cap; and crimp the cap closed with a cap sealing tool.

Test Preparation Transfer 5.0 g, accurately weighed, of the Polysorbate sample to a 22-mL pressure headspace vial, and seal the cap and crimp as directed for the *1,4-Dioxane Standard Preparation*.

Chromatographic System Chromatographic conditions may vary depending on the type of headspace unit used. The gas chromatograph is equipped with a headspace sampler, flame ionization detector, backflush valve, and 1-mL gas sample loop, and it contains a 9-m × 3.2-mm nickel precolumn and a 55-m × 3.2-mm nickel analytical column containing TENAX TA support (60/80-mesh), or equivalent. The column temperature is maintained at 190°, the detector at 250°, and the injector at 250°. The carrier gas is helium at a flow rate of about 30 mL/min. The backflush valve is programmed to initiate backflushing after 1,4-dioxane elutes into the analytical column.

Procedure Place the vial containing the *1,4-Dioxane Standard Preparation* in the automated sampler, and start the operating sequence so that each vial is heated at 90° for a minimum of 30 min. Using appropriate headspace sampler settings, inject the *1,4-Dioxane Standard Preparation*, and measure the peak area for 1,4-dioxane. Similarly, place the vial containing the *Test Preparation* in the automatic sampler, chromatograph its headspace as done for the *1,4-Dioxane Standard Preparation*, and measure the peak area for 1,4-dioxane. The sample passes the test if the peak area of the *Test Preparation* is not greater than that of the *1,4-Dioxane Standard Preparation*.

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.

Lauric Acid Transfer about 25 g of the sample, accurately weighed, into a 500-mL, round-bottom boiling flask, add 250 mL of alcohol and 7.5 g of potassium hydroxide, and mix. Connect a suitable condenser to the flask, reflux the mixture for 1 to 2 h, then transfer to an 800-mL beaker, rinsing the flask with about 100 mL of water and adding it to the beaker. Heat on a steam bath to evaporate the alcohol, adding water occasionally to replace the alcohol, and evaporate until the odor of alcohol can no longer be detected. Adjust the final volume to about 250 mL with hot water. Neutralize the soap solution with dilute sulfuric acid (1 in 2), add 10% in excess, and heat, while stirring, until the fatty acid layer separates. Transfer the fatty acids into a 500-mL separator, wash with three or four 20-mL portions of hot water, and combine the washings with the original aqueous layer from the saponification. Extract the combined aqueous layer with three 50-mL portions of petroleum ether, add the extracts to the fatty acid layer, evaporate to dryness in a tared dish, cool, and weigh. The lauric acid so obtained has an *Acid Value* between 250 and 275 (*Method I*, 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 8 g, accurately weighed.

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

Packaging and Storage Store in tight containers.