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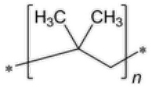
Polyisobutylene



CAS RN®: 9003-27-4.

DEFINITION

Polyisobutylene is a synthetic polymer produced by the low-temperature polymerization of isobutylene in liquid ethylene, methylene chloride, or hexane, using an aluminum-chloride or boron-trifluoride catalyst. It may contain a suitable stabilizer.

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197F**

Analysis: Prepare the sample by dissolving it in hot toluene and evaporating on a salt plate.

Acceptance criteria: Meets the requirements

IMPURITIES

Change to read:

• ▲**Lead ⟨251⟩, *Procedures, Procedure 1*▲** (CN 1-Jun-2023)

Sample: 3.3 g

Control: 10 mL of *Diluted Standard Lead Solution* (10 µg of lead)

Analysis: Transfer the *Sample* to a porcelain dish, and heat on a hot plate until completely charred. Then heat in a muffle furnace at 480° for 8 h, and cool. Cautiously add 5 mL of nitric acid, evaporate to dryness on a hot plate, then heat again in the muffle furnace for exactly 15 min, and cool. Extract the ash with two 10-mL portions of water, filtering the extract into a separator. Leach any insoluble material on the filter with 6 mL of *Ammonium Citrate Solution*, 2 mL of *Hydroxylamine Hydrochloride Solution*, and 5 mL of water, adding the filtered washings to the separator. To the resulting solution and *Control* continue as directed in the chapter for *Procedure*, beginning with “Add 2 drops of phenol red TS”.

Acceptance criteria: NMT 3 µg/g; the color generated by the *Sample* does not exceed that generated by the *Control*.

SPECIFIC TESTS

• **Viscosity—Capillary Methods ⟨911⟩**

Solvent: Use isooctane.

Sample solution: Prepare a solution of Polyisobutylene in the *Solvent* having a known concentration as indicated in *Table 1*. The solution must be homogenous before testing. For the Polyisobutylene having a Staudinger Index of 100 and higher, add the *Solvent* to the weighed material, and allow it to stand in an oven at 80° for 12–24 h. [Note—A heated mechanical shaker may be used to shorten the dissolution time; it is recommended that a gentle shaker be used to avoid shearing the polymers. Take adequate precautions to prevent evaporation of the *Solvent*.]

Table 1

Staudinger Index[a]	Concentration (g/cm^3)
25–60	0.01
60–100	0.005

Staudinger Index[a]	Concentration (g/cm^3)
100–350	0.002
350–700	0.001

[a] The Staudinger Index is equal to 100 times the intrinsic viscosity.

Analysis: Before each measurement, let the solutions be temperature equilibrated for 10 min. Using a suitable Ubbelohde capillary viscometer having dimensions such that the flow time is NLT 200 s, immersed in a controlled temperature bath, measure the flow of the *Solvent* and of the *Sample solution* at 20°. Repeat the *Analysis* three times, and calculate the average.

Calculate the reduced viscosity:

$$J = (t/t_0 - 1)/C$$

t = average flow time of the *Sample solution* (s)

t_0 = average flow time of the *Solvent* (s)

C = concentration of the *Sample solution* (g/cm^3)

Calculate the Staudinger Index:

$$J_0 = J/[1 + 0.31(t/t_0 - 1)]$$

Acceptance criteria: It is within the limits specified on the label.

• **Loss on Drying ⟨731⟩**

Sample: 5 g

Analysis: Dry for 2 h at 105°.

Acceptance criteria: NMT 0.3%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers. No storage requirements specified.

• **Labeling:** Label it to indicate the range for intrinsic viscosity or the range for the Staudinger Index, and the name and quantity of any added stabilizer. [Note—The Staudinger Index is equal to 100 times the intrinsic viscosity.]

• **USP Reference Standards ⟨11⟩**

USP Polyisobutylene RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
POLYISOBUTYLENE	Documentary Standards Support	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

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