tion add 8 mL of dilute nitric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 0.7 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.050%).

(3) Heavy metals—Dissolve 1.0 g of Potassium Hydroxide in 5 mL of water, add 7 mL of dilute hydrochloric acid, and evaporate on a water bath to dryness. Dissolve the residue in 35 mL of water, 2 mL of dilute acetic acid and 1 drop of ammonia TS, add water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution as follows: evaporate 7 mL of dilute hydrochloric acid on a water bath to dryness, dissolve the residue in 2 mL of dilute acetic acid and 3.0 mL of Standard Lead Solution, and add water to make 50 mL (not more than 30 ppm).

(4) Sodium—Dissolve 0.10 g of Potassium Hydroxide in 10 mL of dilute hydrochloric acid, and perform the test as directed under the Flame Coloration Test (1): no persistent yellow color develops.

(5) Potassium carbonate—The amount of potassium carbonate (K_2CO_3: 138.21) is not more than 2.0% when calculated by the following equation using B (mL) obtained in the Assay.

$$\text{Amount of potassium carbonate (mg)} = 138.21 \times B$$

Assay Weigh accurately about 1.5 g of Potassium Hydroxide, and dissolve in 40 mL of freshly boiled and cooled water. Cool the solution to 15°C, add 2 drops of phenolphthalein TS, and titrate with 0.5 mol/L sulfuric acid VS until the red color of the solution disappears. Record the amount A (mL) of 0.5 mol/L sulfuric acid VS consumed, then add 2 drops of methyl orange TS, and titrate again with 0.5 mol/L sulfuric acid VS until the solution changes to a persistent light red color. Record the amount B (mL) of 0.5 mol/L sulfuric acid VS consumed.

Calculate the amount KOH from the amount, A (mL) − B (mL).

Each mL of 0.5 mol/L sulfuric acid VS
= 56.11 mg of KOH

Containers and storage Containers—Tight containers.

Potassium Sulfate

硫酸カリウム

K_2SO_4: 174.26

Potassium Sulfate, when dried, contains not less than 99.0% of K_2SO_4.

Description Potassium Sulfate occurs as colorless crystals or a white, crystalline powder. It has a slightly saline, somewhat bitter taste.

It is soluble in water and practically insoluble in ethanol (95).

Identification A solution of Potassium Sulfate (1 in 20) responds to the Qualitative Tests for potassium salt and for sulfate.

Purity **(1)** Clarity and color of solution, and acid or alkali—Dissolve 1.0 g of Potassium Sulfate in 20 mL of water: the solution is clear, colorless and neutral.

(2) Chloride—Perform the test with 0.5 g of Potassium Sulfate. Prepare the control solution with 0.40 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.028%).

(3) Heavy metals—Proceed with 2.0 g of Potassium Sulfate according to Method 1, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(4) Sodium—Dissolve 1.0 g of Potassium Sulfate in 20 mL of water, and perform the test as directed under the Flame Coloration Test (1): no persistent yellow color develops.

(5) Arsenic—Prepare the test solution with 0.40 g of Potassium Sulfate according to Method 1, and perform the test using Apparatus B (not more than 5 ppm).

Loss on drying Not more than 1.0% (1 g, 110°C, 4 hours).

Assay Weigh accurately about 0.5 g of Potassium Sulfate, previously dried, boil with 200 mL of water and 1.0 mL of hydrochloric acid, and add gradually 8 mL of boiling barium chloride TS. Heat the mixture on a water bath for 1 hour, collect the precipitate, and wash the precipitate with water until the last washing shows no opalescence on the addition of silver nitrate TS. Dry, heat strongly to constant mass between 500°C and 600°C by raising the temperature gradually, and weigh as barium sulfate ($BaSO_4$: 233.39).

Amount (mg) of K_2SO_4
= amount (mg) of barium sulfate ($BaSO_4$) × 0.7466

Containers and storage Containers—Well-closed containers.

Potato Starch

Amylum Solani

バレイショデンプン

Potato Starch consists of starch granules derived from the tuber of *Solanum tuberosum* Linné (*Solanaceae*).

Description Potato Starch occurs as a white powder. It is odorless and tasteless.

Under a microscope, Potato Starch appears as mainly ellipsoid or ovate, simple grains 70 - 90 μm, often 100 μm, in major axis, and rarely as 2-compound an half-compound grains. Hilum is eccentric; striations are distinct.

It is practically insoluble in water and in ethanol (95).

Identification **(1)** To 1 g of Potato Starch add 50 mL of water, boil, and allow to cool: a turbid, neutral and pasty liquid is formed.

(2) To a portion of Potato Starch add iodine TS: a dark blue-purple color develops.

Purity Foreign matter—Under a microscope, Potato Starch does not contain starch grains of any other origin. It may contain a minute quantity, if any, of fragments of the tissue of the original plant.

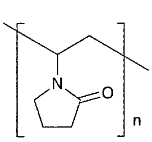
Loss on drying Not more than 18.0% (6 hours).

Total ash Not more than 0.5%.

Povidone

Polyvidone
Polyvinylpyrrolidone
Polyvinylpyrrolidone K25
Polyvinylpyrrolidone K30
Polyvinylpyrrolidone K90

ポビドン



$(C_6H_9NO)_n$
Poly[(2-oxopyrrolidin-1-yl)ethylene] [*9003-39-8*]

Povidone is a chain polymer of 1-vinyl-2-pyrrolidone. It contains not less than 11.5% and not more than 12.8% of nitrogen (N: 14.01), calculated on the anhydrous basis.

It has a nominal K-value of not less than 25 and not more than 90. The nominal K-value is shown on the label.

Description Povidone occurs as a white to slightly yellowish fine powder. It is odorless or has a faint, characteristic odor.

It is freely soluble in water, in methanol and in ethanol (95), slightly soluble in acetone, and practically insoluble in diethyl ether.

It is hygroscopic.

Identification Determine the infrared absorption spectrum of Povidone, previously dried at 105°C for 6 hours, as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of Povidone Reference Standard previously dried at 105°C for 6 hours: both spectra exhibit similar intensities of absorption at the same wave numbers.

pH Dissolve 1.0 g of Povidone in 20 mL of water: the pH of this solution is between 3.0 and 5.0 for Povidone having the nominal K-value of 30 or less, and between 4.0 and 7.0 for Povidone having the nominal K-value exceeding 30.

Purity **(1)** Clarity and color of solution—Dissolve 1.0 g of Povidone in 20 mL of water: the solution is clear and colorless to pale yellow, or pale red.

(2) Heavy metals—Proceed with 2.0 g of Povidone according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(3) Aldehydes—Weigh accurately about 1.0 g of Povidone and dissolve in 0.3 mol/L pyrophosphate buffer solution, pH 9.0 to make exactly 100 mL. Stopper, heat at 60°C for 60 minutes, allow to cool to room temperature, and use this solution as the sample solution. Separately, dissolve 0.100 g of freshly distilled acetaldehyde in water previously cooled to 4°C to make exactly 100 mL. Allow to stand at 4°C for about 20 hours, pipet 1 mL of this solution, add 0.3 mol/L pyrophosphate buffer solution, pH 9.0 to make exactly 100 mL, and use this solution as the standard solution. Measure 0.5 mL each of the sample solution, standard solution and water (for blank test), transfer to separate cells, add 2.5 mL of 0.3 mol/L pyrophosphate buffer solution, pH 9.0, and 0.2 mL of *β*-nicotinamide adenine dinucleotide TS to each of these cells, mix and stopper tightly. Allow to stand for 2 to 3 minutes at 22 ± 2°C, and perform the test with these solutions as directed under the Ultraviolet-visible Spectrophotometry using water as the control solution. Determine the absorbances, A_{T1}, A_{S1} and A_{B1} of the subsequent solutions of the sample solution, the standard solution and water at 340 nm. Add 0.05 mL of aldehyde dehydrogenase solution to each of the cells, mix and stopper tightly. Allow to stand for 5 minutes at 22 ± 2°C. Determine the absorbances, A_{T2}, A_{S2} and A_{B2} of these solutions in the same manner as above: the content of aldehydes is not more than 500 ppm (expressed as acetaldehyde).

$$\text{Content (ppm) of aldehydes expressed as acetaldehyde} = \frac{(A_{T2} - A_{T1}) - (A_{B2} - A_{B1})}{(A_{S2} - A_{S1}) - (A_{B2} - A_{B1})} \times \frac{1000}{W}$$

W: Weighed amount (g) of povidone, calculated on the anhydrous basis.

(4) 1-Vinyl-2-pyrrolidone—Weigh accurately about 0.25 g of Povidone, dissolve in diluted methanol (1 in 5) to make exactly 10 mL, and use this solution as the sample solution. Separately, dissolve 0.050 g of 1-vinyl-2-pyrrolidone in methanol to make exactly 100 mL. Pipet 1 mL of this solution and add methanol to make exactly 100 mL. Pipet 5 mL of this solution, add diluted methanol (1 in 5) to make exactly 100 mL, and use this solution as the standard solution. Perform the test with 50 *μ*L each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions, and determine the peak areas, A_T and A_S, of 1-vinyl-2-pyrrolidone in each solution: the content of 1-vinyl-2-pyrrolidone is not more than 10 ppm.

$$\text{Content (ppm) of 1-vinyl-2-pyrrolidone} = \frac{A_T}{A_S} \times \frac{2.5}{W}$$

W: Weighed amount (g) of Povidone, calculated on the anhydrous basis.

Operating conditions—

Detector: An ultraviolet spectrophotometer (detection wavelength: 254 nm).

Column: Stainless steel columns about 4 mm in inside diameter and about 25 mm in length, and about 4 mm in inside diameter and about 250 mm in length, packed with octylsilanized silica gel for liquid chromatography (5 *μ*m in particle diameter), and use them as a guard column and a separation column, respectively.

Column temperature: A constant temperature of about 40°C.

Mobile phase: A mixture of water and methanol (4:1).

Flow rate: Adjust the flow rate so that the retention time