

**Content:** 98.0 per cent to 101.0 per cent (anhydrous substance).

**01/2008:0618**  
**corrected 6.0**

## CHARACTERS

**Appearance:** white or almost white, crystalline powder or colourless, transparent crystals.

**Solubility:** very soluble in water, practically insoluble in alcohol.

## IDENTIFICATION

- It complies with the test for specific optical rotation (see Tests).
- It gives reaction (b) of tartrates (2.3.1).
- It gives reaction (b) of potassium (2.3.1).
- It gives reaction (a) of sodium (2.3.1).

## TESTS

**Solution S.** Dissolve 5.000 g in *carbon dioxide-free water R*, prepared from *distilled water R*, and dilute to 100.0 ml with the same solvent.

**Appearance of solution.** Solution S is clear (2.2.1) and colourless (2.2.2, *Method II*).

**Acidity or alkalinity.** To 5 ml of solution S, add 0.1 ml of *phenolphthalein solution R*. Not more than 0.5 ml of 0.01 M *hydrochloric acid* or 0.01 M *sodium hydroxide* is required to change the colour of the indicator.

**Specific optical rotation** (2.2.7): + 28.0 to + 30.0 (anhydrous substance), determined on solution S.

**Chlorides** (2.4.4): maximum 100 ppm.

Dilute 10 ml of solution S to 15 ml with *water R*. The solution complies with the limit test for chlorides.

**Sulphates** (2.4.13): maximum 50 ppm.

Dissolve 1.0 g in *distilled water R* and dilute to 15 ml with the same solvent. The solution complies with the limit test for sulphates. Prepare the reference solution with a mixture of 5 ml of *sulphate standard solution* (10 ppm  $\text{SO}_4$ ) *R* and 10 ml of *distilled water R*.

**Ammonium** (2.4.1): maximum 40 ppm.

5 ml of solution S complies with the limit test for ammonium.

**Barium and oxalates.** To 5 ml of solution S, add 3 ml of *calcium sulphate solution R*. Allow to stand for 5 min. Any opalescence in the solution is not more intense than that in a mixture of 3 ml of *calcium sulphate solution R* and 5 ml of *distilled water R*.

**Calcium** (2.4.3): maximum 200 ppm.

Dilute 10 ml of solution S to 15 ml with *distilled water R*. The solution complies with the limit test for calcium.

**Heavy metals** (2.4.8): maximum 10 ppm.

Dissolve 2.0 g in *water R* and dilute to 20 ml with the same solvent. 12 ml of the solution complies with limit test A. Prepare the standard using *lead standard solution* (1 ppm Pb) *R*.

**Water** (2.5.12): 24.0 per cent to 26.5 per cent, determined on 50.0 mg. Use 50 ml of *anhydrous methanol R*. Titrate slowly.

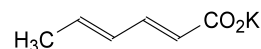
## ASSAY

To 0.100 g of finely powdered substance add 40 ml of *anhydrous acetic acid R* and 20 ml of *acetic anhydride R*. Titrate slowly with 0.1 M *perchloric acid*, determining the end-point potentiometrically (2.2.20).

1 ml of 0.1 M *perchloric acid* is equivalent to 10.51 mg of  $\text{C}_6\text{H}_7\text{KO}_2$ .

# POTASSIUM SORBATE

## Kalii sorbas



$\text{C}_6\text{H}_7\text{KO}_2$   
[590-00-1]

$M_r$  150.2

## DEFINITION

Potassium (*E,E*)-hexa-2,4-dienoate.

**Content:** 99.0 per cent to 101.0 per cent (dried substance).

## CHARACTERS

**Appearance:** white or almost white powder or granules.

**Solubility:** very soluble in water, slightly soluble in ethanol (96 per cent).

## IDENTIFICATION

**First identification:** B, D.

**Second identification:** A, C, D.

- Ultraviolet and visible absorption spectrophotometry (2.2.25).

**Test solution.** Dissolve 50.0 mg in *water R* and dilute to 250.0 ml with the same solvent. Dilute 2.0 ml of this solution to 200.0 ml with 0.1 M *hydrochloric acid*.

**Spectral range:** 230-350 nm.

**Absorption maximum:** at 264 nm.

**Specific absorbance at the absorption maximum:** 1650 to 1900.

- Infrared absorption spectrophotometry (2.2.24).

**Comparison:** *potassium sorbate CRS*.

- Dissolve 1.0 g in 50 ml of *water R*, add 10 ml of *dilute hydrochloric acid R* and shake. Filter the crystalline precipitate, wash with *water R* and dry *in vacuo* over *sulphuric acid R* for 4 h. The residue obtained melts (2.2.14) at 132 °C to 136 °C.

- Dissolve 0.2 g in 2 ml of *water R* and add 2 ml of *dilute acetic acid R*. Filter. The solution gives reaction (b) of potassium (2.3.1).

## TESTS

**Solution S.** Dissolve 2.5 g in *carbon dioxide-free water R* and dilute to 50 ml with the same solvent.

**Appearance of solution.** Solution S is clear (2.2.1) and not more intensely coloured than reference solution  $Y_5$  (2.2.2, *Method II*).

**Acidity or alkalinity.** To 20 ml of solution S add 0.1 ml of *phenolphthalein solution R*. Not more than 0.25 ml of 0.1 M *sodium hydroxide* or 0.1 M *hydrochloric acid* is required to change the colour of the indicator.

**Aldehydes:** maximum 0.15 per cent, expressed as  $\text{C}_2\text{H}_4\text{O}$ .

Dissolve 1.0 g in a mixture of 30 ml of *water R* and 50 ml of *2-propanol R*, adjust to pH 4 with 1 M *hydrochloric acid* and dilute to 100 ml with *water R*. To 10 ml of the solution add 1 ml of *decolorised fuchsin solution R* and allow to stand for 30 min. Any colour in the solution is not more intense than that in a standard prepared at the same time by adding 1 ml of *decolorised fuchsin solution R* to a mixture of 1.5 ml of *acetaldehyde standard solution* (100 ppm  $\text{C}_2\text{H}_4\text{O}$ ) *R*, 4 ml of *2-propanol R* and 4.5 ml of *water R*.

**Heavy metals** (2.4.8): maximum 10 ppm.

2.0 g complies with test D. Prepare the reference solution using 2 ml of *lead standard solution* (10 ppm Pb) R.

**Loss on drying** (2.2.32): maximum 1.0 per cent, determined on 1.000 g by drying in an oven at 105 °C for 3 h.

#### ASSAY

Dissolve 0.120 g in 20 ml of *anhydrous acetic acid* R. Titrate with 0.1 M *perchloric acid* using 0.1 ml of *crystal violet solution* R as indicator until the colour changes from violet to bluish-green.

1 ml of 0.1 M *perchloric acid* is equivalent to 15.02 mg of  $C_6H_7KO_2$ .

#### STORAGE

Protected from light.

01/2008:1622  
corrected 6.0

## POTASSIUM SULPHATE

### Kalii sulfas

$K_2SO_4$   
[7778-80-5]

$M_r$  174.3

#### DEFINITION

**Content:** 98.5 per cent to 101.0 per cent of  $K_2SO_4$  (dried substance).

#### CHARACTERS

**Appearance:** white or almost white, crystalline powder or colourless crystals.

**Solubility:** soluble in water, practically insoluble in ethanol.

#### IDENTIFICATION

A. It gives the reactions of sulphates (2.3.1).

B. It gives the reactions of potassium (2.3.1).

#### TESTS

**Solution S.** Dissolve 10.0 g in 90 ml of *carbon dioxide-free water* R prepared from *distilled water* R, heating gently. Allow to cool and dilute to 100 ml with *carbon dioxide-free water* R prepared from *distilled water* R.

**Appearance of solution.** Solution S is clear (2.2.1) and colourless (2.2.2, *Method II*).

**Acidity or alkalinity.** To 10 ml of solution S add 0.1 ml of *bromothymol blue solution* R1. Not more than 0.5 ml of 0.01 M *hydrochloric acid* or 0.01 M *sodium hydroxide* is required to change the colour of the indicator.

**Chlorides** (2.4.4): maximum 40 ppm.

Dilute 12.5 ml of solution S to 15 ml with *water* R.

**Calcium** (2.4.3): maximum 200 ppm.

Dilute 5 ml of solution S to 15 ml with *distilled water* R.

**Iron** (2.4.9): maximum 10 ppm, determined on 10 ml of solution S.

**Magnesium:** maximum 20 ppm.

To 5 ml of solution S add 5 ml of *water* R, 1 ml of *glycerol* (85 per cent) R, 0.15 ml of *titan yellow solution* R, 0.25 ml of *ammonium oxalate solution* R and 5 ml of *dilute sodium hydroxide solution* R and shake. Any pink colour in the test solution is not more intense than that in a standard prepared

at the same time and in the same manner using a mixture of 1 ml of *magnesium standard solution* (10 ppm Mg) R and 9 ml of *water* R.

**Sodium:** maximum 0.10 per cent.

Atomic emission spectrometry (2.2.22, *Method I*).

**Test solution.** Dissolve 1.00 g of the substance to be examined in *water* R and dilute to 100.0 ml with the same solvent.

**Reference solutions.** Dissolve in *water* R 0.50 g of *sodium chloride* R, previously dried at 100-105 °C for 3 h, and dilute to 1000.0 ml with the same solvent (200 µg of Na per millilitre). Dilute as required.

**Wavelength:** 589 nm.

**Heavy metals** (2.4.8): maximum 20 ppm.

12 ml of solution S complies with limit test A. Prepare the standard using *lead standard solution* (2 ppm Pb) R.

**Loss on drying** (2.2.32): maximum 1.0 per cent, determined on 1.000 g by drying in an oven at 130 °C for 4 h.

#### ASSAY

Dissolve 0.150 g in 40 ml of *water* R. Add 0.2 ml of 0.1 M *hydrochloric acid* and 80 ml of *methanol* R. Carry out a potentiometric titration (2.2.20), using 0.1 M *lead nitrate* and as indicator electrode a lead-selective electrode and as reference electrode a silver-silver chloride electrode.

1 ml of 0.1 M *lead nitrate* is equivalent to 17.43 mg of  $K_2SO_4$ .

01/2008:0355  
corrected 6.0

## POTATO STARCH

### Solani amyllum

#### DEFINITION

Potato starch is obtained from the tuber of *Solanum tuberosum* L.

#### CHARACTERS

**Appearance:** very fine, white or almost white powder which creaks when pressed between the fingers.

**Solubility:** practically insoluble in cold water and in alcohol. Potato starch does not contain starch grains of any other origin. It may contain a minute quantity, if any, of tissue fragments of the original plant.

#### IDENTIFICATION

- Examined under a microscope using a mixture of equal volumes of *glycerol* R and *water* R, it presents granules, either irregularly shaped, ovoid or pear-shaped, usually 30 µm to 100 µm in size but occasionally exceeding 100 µm, or rounded, 10 µm to 35 µm in size. There are occasional compound granules having 2 to 4 components. The ovoid and pear-shaped granules have an eccentric hilum and the rounded granules acentric or slightly eccentric hilum. All granules show clearly visible concentric striations. Between crossed nicol prisms, the granules show a distinct black cross intersecting at the hilum.
- Suspend 1 g in 50 ml of *water* R, boil for 1 min and cool. A thick, opalescent mucilage is formed.
- To 1 ml of the mucilage obtained in identification test B, add 0.05 ml of *iodine solution* R1. An orange-red to dark blue colour is produced which disappears on heating.