ACESULFAME POTASSIUM

Prepared at the 57th JECFA (2001) and published in FNP 52 Add 9 (2001), superseding specifications prepared at the 46th JECFA (1996) and published in FNP 52 Add 4 (1996). An ADI of 0-15 mg/kg body weight was established at the 37th JECFA (1990).

SYNONYMS Acesulfame K; INS No. 950

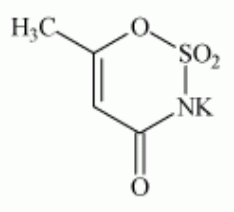
DEFINITION

Chemical names: Potassium salt of 6-methyl-1,2,3-oxathiazine-4(3H)-one-2,2-dioxide; potassium salt of 3,4-dihydro-6-methyl-1,2,3-oxathiazine-4-one-2,2-dioxide

C.A.S. number: 55589-62-3

Chemical formula: $C_4H_4KNO_4S$

Structural formula:



Formula weight: 201.24

Assay: Not less than 99.0% and not more than 101.0% on the dried basis

DESCRIPTION Odourless, white crystalline powder

FUNCTIONAL USES Sweetener, flavour enhancer

CHARACTERISTICS

IDENTIFICATION

Solubility (Vol. 4): Freely soluble in water, very slightly soluble in ethanol

Spectrophotometry: Dissolve 10 mg of the sample in 1,000 ml of water. The solution shows an absorbance maximum at 227±2 nm

Test for potassium (Vol.4): Passes test
Test the residue obtained by igniting 2 g of the sample

Precipitation test: Add a few drops of a 10% solution of sodium cobaltinitrite to a solution of 0.2 g of the sample in 2 ml of acetic acid TS and 2 ml of water. A yellow precipitate is produced.

PURITY

Loss on drying (Vol. 4)	Not more than 1.0% (105°, 2 h)
pH (Vol. 4)	5.5 - 7.5 (1% soln)
Organic impurities	Passes test for 20 mg/kg of UV active components See description under TESTS
Fluoride (Vol. 4)	Not more than 3 mg/kg Method III; using an appropriate sample size and appropriate volumes of the standard solution for construction of the calibration curve.
Lead (Vol. 4)	Not more than 1 mg/kg Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in Volume 4, “Instrumental Methods.”

TESTS

PURITY TESTS

Organic impurities

Proceed as directed under the method for Chromatography (High Performance Liquid Chromatography, FNP 5) using the following conditions and using 4-hydroxybenzoic acid ethyl ester as the reference substance:

Column: 25 cm x 4.6 mm stainless steel
Stationary phase: Reversed phase (C18 silica gel, 3 - 5 µm)
Elution: Isocratic
Mobile phase: Acetonitrile/0.01 mol/l tetrabutyl ammonium hydrogen sulfate (TBAHS) in water; 40/60 v/v
Flow: About 1 ml/min
Detector type: UV or Diode array, 227 nm
Sample size: 20 µl of a 10 g/l solution of the sample in deionized water

The chromatographic system must be capable of separating acesulfame K and 4-hydroxybenzoic acid ethyl ester with a resolution of 2.
If peaks other than that due to acesulfame K appear within three times the elution time of acesulfame K, carry out a second run using 20 µl of a 0.2 mg/l solution of the sample.

The sum of the areas of all peaks eluted in the first run within 3 times the elution time of acesulfame K elution time, except for the acesulfame K peak, does not exceed the peak area of acesulfame K in the second run.

METHOD OF ASSAY

Dissolve about 0.15 g of the dried sample (dissolution may be slow), accurately weighed, in 50.0 ml glacial acetic acid and titrate potentiometrically with 0.1 N perchloric acid, or add two drops of crystal violet TS and titrate with 0.1 N perchloric acid, to a blue-green end-point which persists for at least 30 sec. Perform a blank determination and make any necessary correction. Each ml of 0.1 N perchloric acid is equivalent to 20.12 mg of $C_4H_4KNO_4S$.