

Potassium Bicarbonate

1 Nonproprietary Names

BP: Potassium bicarbonate
PhEur: Kalii hydrogenocarbonas
USPNF: Potassium bicarbonate

2 Synonyms

Carbonic acid monopotassium salt; E501; monopotassium carbonate; potassium acid carbonate; potassium hydrogen carbonate.

3 Chemical Name and CAS Registry Number

Potassium bicarbonate [298-14-6]

4 Empirical Formula Molecular Weight

KHCO_3 100.11

5 Structural Formula

KHCO_3

6 Functional Category

Alkalinizing agent; therapeutic agent.

7 Applications in Pharmaceutical Formulation or Technology

As an excipient, potassium bicarbonate is generally used in formulations as a source of carbon dioxide in effervescent preparations, at concentrations of 25–50% w/w. It is of particular use in formulations where sodium bicarbonate is unsuitable, for example, when the presence of sodium ions in a formulation needs to be limited or is undesirable. Potassium bicarbonate is often formulated with citric acid or tartaric acid in effervescent tablets or granules; on contact with water, carbon dioxide is released through chemical reaction, and the product disintegrates. On occasion, the presence of potassium bicarbonate alone may be sufficient in tablet formulations, as reaction with gastric acid can be sufficient to cause effervescence and product disintegration.

More recently, potassium bicarbonate has been investigated as a gas-forming agent in alginate raft systems.^(1,2)

Potassium bicarbonate is also used in food applications as an alkali and a leavening agent, and is a component of baking powder.

Therapeutically, potassium bicarbonate is used as an alternative to sodium bicarbonate in the treatment of certain types of metabolic acidosis. It is also used as an antacid to neutralize acid secretions in the gastrointestinal tract and as a potassium supplement.

8 Description

Potassium bicarbonate occurs as colorless, transparent crystals or as a white granular or crystalline powder. It is odorless, with a saline or weakly alkaline taste.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for potassium bicarbonate.

Test	PhEur 2002	USPNF 20
Identification	+	+
Characters	+	—
Appearance	+	—
Carbonates/normal carbonate	+	≤0.001%
Normal carbonates	—	≤2.5%
Chloride	≤150 ppm	—
Sulfate	≤150 ppm	—
Ammonium	≤20 ppm	—
Calcium	≤100 ppm	—
Heavy metals	≤10 ppm	≤0.001%
Iron	≤20 ppm	—
Sodium	≤0.5%	—
Loss on drying	—	≤0.3%
Organic volatile impurities	—	+
Assay	99.0–101.0%	99.5–101.5%

10 Typical Properties

Acidity/alkalinity: pH = 8.2 (for a 0.1 M aqueous solution)

Solubility: soluble 1 in 4.5 of water at 0°C, 1 in 2.8 of water at 20°C, 1 in 2 of water at 50°C; practically insoluble in ethanol (95%).

Specific gravity: 2.17

11 Stability and Storage Conditions

Potassium bicarbonate should be stored in a well-closed container in a cool, dry location. Potassium bicarbonate is stable in air at normal temperatures, but when heated to 100–200°C in the dry state, or in solution, it is gradually converted to potassium carbonate.

12 Incompatibilities

Potassium bicarbonate reacts with acids and acidic salts with the evolution of carbon dioxide.

13 Method of Manufacture

Potassium bicarbonate can be made by passing carbon dioxide into a concentrated solution of potassium carbonate, or by exposing moist potassium carbonate to carbon dioxide, preferably under moderate pressure.

Potassium bicarbonate also occurs naturally in the mineral calcinite.

14 Safety

Potassium bicarbonate is used in cosmetics, foods, and oral pharmaceutical formulations, where it is generally regarded as a relatively nontoxic and nonirritant material when used as an excipient. However, excessive consumption of potassium bicarbonate or other potassium salts may produce toxic manifestations of hyperkalemia.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection and gloves are recommended.

16 Regulatory Status

GRAS listed. Accepted as a food additive in Europe (the E number E501 refers to potassium carbonates). Included in nonparenteral medicines licensed in the UK and USA (chewable tablets; effervescent granules; effervescent tablets; oral granules; oral suspensions).

17 Related Substances

Sodium bicarbonate.

18 Comments

One gram of potassium bicarbonate represents approximately 10 mmol of potassium and of bicarbonate; 2.56 g of potassium bicarbonate is approximately equivalent to 1 g of potassium.

The EINECS number for potassium bicarbonate is 206-059-0.

19 Specific References

- 1 Johnson FA, Craig DQM, Mercer AD, Chauhan S. The effects of alginate molecular structure and formulation variables on the physical characteristics of alginate raft systems. *Int J Pharm* 1997; 159: 35–42.
- 2 Johnson FA, Craig DQM, Mercer A, Chauhan S. The use of image analysis as a means of monitoring bubble formation in alginate rafts. *Int J Pharm* 1998; 170: 179–185.

20 General References

—

21 Author

CG Cable.

22 Date of Revision

22 November 2002.