Potassium Hydroxide

1 Nonproprietary Names

BP: Potassium hydroxide JP: Potassium hydroxide PhEur: Kalii hydroxidum USPNF: Potassium hydroxide

2 Synonyms

Caustic potash; E525; kalium hydroxydatum; potash lye; potassium hydrate.

3 Chemical Name and CAS Registry Number

Potassium hydroxide [1310-58-3]

| 4 | Empirical Formula | Molecular Weight |
|----|--------------------------|------------------|
| KC | ЭН | 56.11 |

5 Structural Formula

KOH

6 Functional Category

Alkalizing agent.

7 Applications in Pharmaceutical Formulation or Technology

Potassium hydroxide is widely used in pharmaceutical formulations to adjust the pH of solutions. It can also be used to react with weak acids to form salts.

Therapeutically, potassium hydroxide is used in various dermatological applications.

8 Description

Potassium hydroxide occurs as a white or nearly white fused mass. It is available in small pellets, flakes, sticks and other shapes or forms. It is hard and brittle and shows a crystalline fracture. Potassium hydroxide is hygroscopic and deliquescent; on exposure to air, it rapidly absorbs carbon dioxide and water with the formation of potassium carbonate.

9 Pharmacopeial Specifications

See Table I.

10 Typical Properties

Acidity/alkalinity: pH = 13.5 (0.1 M aqueous solution) Melting point: 360 °C; 380 °C when anhydrous Solubility: see Table II.

Table 1: Pharmacopeial specifications for potassium hydroxide.

| Test | JP 2001 | PhEur 2002 | USPNF 20 |
|------------------------|---------|-------------|----------|
| Identification | + | + | + |
| Appearance of solution | + | + | _ |
| Aluminum | _ | <0.2 ppm | |
| Characters | | + | |
| Chloride | ≤0.05% | <50 ppm | _ |
| Heavy metals | <30 ppm | ≤10 ppm | ≤0.003% |
| Insoluble substances | | | + |
| Iron | _ | ≤10 ppm | _ |
| Phosphates | _ | ≤20 ppm | _ |
| Potassium carbonate | ≤2.0% | €2.0% | _ |
| Sodium | + | ≤1.0% | |
| Sulfates | | <50 ppm | |
| Assay | ≥85.0% | 85.0–100.5% | ≥85.0% |

Table II: Solubility of potassium hydroxide.

| Solvent | Solubility at 20 °C unless otherwise stated | | |
|---------------|---|--|--|
| Ethanol (95%) | 1 in 3 | | |
| Ether | Practically insoluble | | |
| Glycerin | 1 in 2.5 | | |
| Water | 1 in 0.9 | | |
| | 1 in 0.6 at 100 °C | | |

11 Stability and Storage Conditions

Potassium hydroxide should be stored in an airtight, non-metallic container in a cool, dry place.

12 Incompatibilities

Potassium hydroxide is a strong base and is incompatible with any compound that readily undergoes hydrolysis or oxidation. It should not be stored in glass or aluminum containers and will react with acids, esters, and ethers, especially in aqueous solution.

13 Method of Manufacture

Potassium hydroxide is made by the electrolysis of potassium chloride. Commercial grades may contain chlorides as well as other impurities.

14 Safety

Potassium hydroxide is widely used in the pharmaceutical and food industries and is generally regarded as a nontoxic material at low concentrations. At high concentrations it is a corrosive irritant to the skin, eyes, and mucous membranes.

LD₅₀ (rat, oral): 0.273 g/kg⁽¹⁾

15 Handling Precautions

Potassium hydroxide is a corrosive irritant to the skin, eyes, and mucous membranes. The solid and solutions cause burns, often with deep ulceration. It is very toxic on ingestion and harmful on inhalation. Observe normal handling precautions appropriate to the quantity and concentration of material handled. Gloves, eye protection, respirator, and other protective clothing should be worn.

Potassium hydroxide is strongly exothermic when dissolved in ethanol (95%) or water and considerable heat is generated. The reaction between potassium hydroxide solutions and acids is also strongly exothermic.

In the UK, the occupational exposure limit for potassium hydroxide has been set at 2 mg/m³ short-term.⁽²⁾

16 Regulatory Status

GRAS listed. Accepted for use in Europe in certain food applications. Included in the FDA Inactive Ingredients Guide (injections, infusions, and oral capsules and solutions). Included in nonparenteral and parenteral medicines licensed in the UK.

17 Related Substances

Sodium hydroxide.

18 Comments

The EINECS number for potassium hydroxide is 215-181-3.

19 Specific References

- 1 Lewis RJ, ed. Sax's Dangerous Properties of Industrial Materials, 10th edn. New York: Wiley, 2000: 3032.
- 2 Health and Safety Executive. EH40/2002: Occupational Exposure Limits 2002. Sudbury: HSE Books, 2002.

20 General References

21 Author

AH Kibbe.

22 Date of Revision

26 June 2002.