

# Sodium Hydroxide

## 1 Nonproprietary Names

BP: Sodium hydroxide  
JP: Sodium hydroxide  
PhEur: Natrii hydroxidum  
USPNF: Sodium hydroxide

## 2 Synonyms

Caustic soda; E524; lye; soda lye; sodium hydrate.

## 3 Chemical Name and CAS Registry Number

Sodium hydroxide [1310-73-2]

## 4 Empirical Formula

NaOH

## Molecular Weight

40.00

## 5 Structural Formula

NaOH

## 6 Functional Category

Alkalizing agent; buffering agent.

## 7 Applications in Pharmaceutical Formulation or Technology

Sodium hydroxide is widely used in pharmaceutical formulations to adjust the pH of solutions.<sup>(1)</sup> It can also be used to react with weak acids to form salts.

## 8 Description

Sodium 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. Sodium hydroxide is very deliquescent and on exposure to air it rapidly absorbs carbon dioxide and water.

## 9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for sodium hydroxide.

Test	JP 2001	PhEur 2002	USPNF 20
Identification	+	+	+
Characters	—	+	—
Appearance of solution	+	+	—
Insoluble substances and organic matter	—	—	+
Sodium carbonate	≤2.0%	≤2.0%	—
Sulfates	—	≤50 ppm	—
Chlorides	≤0.05%	≤50 ppm	—
Iron	—	≤10 ppm	—
Mercury	+	—	—
Heavy metals	≤30 ppm	≤20 ppm	≤0.003%
Potassium	+	—	+
Assay (total alkali calculated as NaOH)	≥95.0%	97.0–100.5%	95.0–100.5%

## 10 Typical Properties

Acidity/alkalinity:

pH ≈ 12 (0.05% w/w aqueous solution)

pH ≈ 13 (0.5% w/w aqueous solution)

pH ≈ 14 (5% w/w aqueous solution)

Melting point: 318 °C

Solubility: see Table II.

Table II: Solubility of sodium hydroxide.

Solvent	Solubility at 20 °C unless otherwise stated
Ethanol	1 in 7.2
Ether	Practically insoluble
Glycerin	Soluble
Methanol	1 in 4.2
Water	1 in 0.9
	1 in 0.3 at 100 °C

## 11 Stability and Storage Conditions

Sodium hydroxide should be stored in an airtight nonmetallic container in a cool, dry place. When exposed to air, sodium hydroxide rapidly absorbs moisture and liquefies, but subsequently becomes solid again owing to absorption of carbon dioxide and formation of sodium carbonate.

## 12 Incompatibilities

Sodium hydroxide is a strong base and is incompatible with any compound that readily undergoes hydrolysis or oxidation. It will react with acids, esters, and ethers, especially in aqueous solution.

### 13 Method of Manufacture

Sodium hydroxide is manufactured by electrolysis of brine using inert electrodes. Chlorine is evolved as a gas at the anode and hydrogen is evolved as a gas at the cathode. The removal of chloride and hydrogen ions leaves sodium and hydroxide ions in solution. The solution is dried to produce the solid sodium hydroxide.

A second method uses the Kellner–Solvay cell. Saturated sodium chloride solution is electrolyzed between a carbon anode and a flowing mercury cathode. In this case the sodium is produced at the cathode rather than the hydrogen because of the readiness of sodium to dissolve in the mercury. The sodium–mercury amalgam is then exposed to water and a sodium hydroxide solution is produced.

### 14 Safety

Sodium 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.

LD<sub>50</sub> (mouse, IP): 0.04 g/kg<sup>(2)</sup>

LD<sub>50</sub> (rabbit, oral): 0.5 g/kg

### 15 Handling Precautions

Observe normal handling precautions appropriate to the quantity and concentration of material handled. Gloves, eye protection, a respirator, and other protective clothing should be worn.

Sodium hydroxide is a corrosive irritant to the skin, eyes, and mucous membranes. The solid and solutions cause burns, often with deep ulceration. It is moderately toxic on ingestion and harmful on inhalation.

In the UK, the occupational exposure limit for sodium hydroxide has been set at 2 mg/m<sup>3</sup> short-term.<sup>(3)</sup>

### 16 Regulatory Status

GRAS listed. Accepted for use in certain food applications in Europe. Included in the FDA Inactive Ingredients Guide

(injections; inhalations; nasal, ophthalmic, oral, otic, rectal, topical, and vaginal preparations). Included in nonparenteral and parenteral medicines licensed in the UK.

### 17 Related Substances

Potassium hydroxide.

### 18 Comments

Sodium hydroxide is most commonly used in solutions of fixed concentration. Sodium hydroxide has some antibacterial and antiviral properties and is used as a disinfectant in some applications.<sup>(4-6)</sup>

The EINECS number for sodium hydroxide is 215-185-5.

### 19 Specific References

- 1 Zhan X, Yin G, Ma B. Improved stability of 25% vitamin C parenteral formulation. *Int J Pharm* 1998; 173: 43–49.
- 2 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 10th edn. New York: Wiley, 2000: 3253.
- 3 Health and Safety Executive. *EH40/2002: Occupational Exposure Limits 2002*, Sudbury: Health and Safety Executive, 2002.
- 4 Brown P, Rohmer RG, Gajduseck DC. Sodium hydroxide decontamination of Creutzfeldt–Jakob disease virus. *N Engl J Med* 1984; 320: 727.
- 5 Gasser G. Creutzfeldt–Jakob disease [letter]. *Br Med J* 1990; 300: 1523.
- 6 Perkowski CA. Operational aspects of bioreactor contamination control. *J Parenter Sci Technol* 1990; 44: 113–117.

### 20 General References

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### 21 Author

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### 22 Date of Revision

26 June 2002.