

Potassium Nitrate

1 Nonproprietary Names

BP: Potassium Nitrate
PhEur: Potassium Nitrate
USP-NF: Potassium Nitrate

2 Synonyms

E252; kalii nitras; kalium nitricum; niter; nitrate of potash; nitric acid, potassium salt; saltpeter.

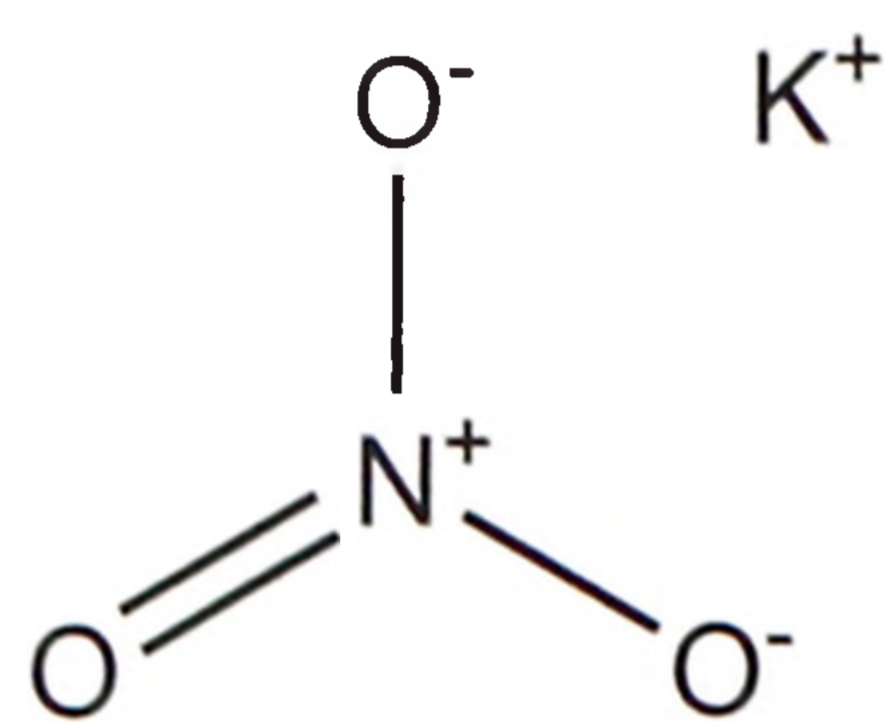
3 Chemical Name and CAS Registry Number

Potassium nitrate [7757-79-1]

4 Empirical Formula and Molecular Weight

KNO₃ 101.1

5 Structural Formula



6 Functional Category

Antimicrobial preservative.

7 Applications in Pharmaceutical Formulation or Technology

Potassium nitrate is used as a preservative in eye lotions and eye drops. It is widely used in foods and oral care products; *see* Section 18.

8 Description

Potassium nitrate occurs as a white or almost white crystalline powder or colorless crystals, with a cooling, saline, pungent taste.

9 Pharmacopeial Specifications

See Table I.

10 Typical Properties

Acidity/alkalinity pH = 6.2 at 14°C for 10% aqueous solution

Boiling point 400°C

Density 2.11 g/cm³

Melting point 333°C

Solubility Freely soluble in water; very soluble in boiling water; practically insoluble in alcohol; soluble in glycerol.

11 Stability and Storage Conditions

Potassium nitrate is considered to be a stable material; however, it may decompose if heated. Store in airtight containers in a cool, well-ventilated place.

Table I: Pharmacopeial specifications for potassium nitrate.

Test	PhEur 9.2	USP 40-NF 35 S1
Characters	+	—
Identification	+	+
Appearance of solution	+	—
Acidity or alkalinity	+	—
Reducible substances	+	—
Chlorides	≤20 ppm ^(a)	≤0.03%
Sulfates	≤150 ppm	≤0.1%
Ammonium	≤100 ppm ^(b)	—
Calcium	≤100 ppm ^(b)	—
Iron	≤20 ppm ^(c)	≤10 ppm
Sodium	≤0.1%	≤0.1%
Lead	—	≤10 ppm
Heavy metals	—	≤20 ppm
Loss on drying	≤0.5%	—
Limit of nitrite	—	≤5 μg/g
Assay (dried substance)	99.0–101.0%	99.0–100.5%

(a) If for ophthalmic use.

(b) ≤50 ppm if for ophthalmic use.

(c) ≤10 ppm if for ophthalmic use.

12 Incompatibilities

Potassium nitrate is incompatible with reducing agents, strong acids, metals and organic compounds. An explosive reaction occurs with potassium chlorate or bromine trifluoride.

13 Method of Manufacture

Potassium nitrate is produced by double decomposition of sodium nitrate with potassium chloride.

14 Safety

Potassium nitrate is used as a food additive and in oral and eyecare products, and is therefore regarded as a safe material when applied appropriately for these uses.

However, potassium nitrate in its pure form is irritating to the respiratory tract, and may cause coughing and shortness of breath. It is also irritating to the skin and eyes, causing redness, itching, and pain. Ingestion of large quantities may cause violent gastroenteritis. Prolonged exposure to small amounts may produce anemia, methemoglobinemia, and nephritis.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has reviewed the safety of potassium nitrate and recommended an acceptable daily intake of up to 3.7 mg/kg body weight daily, expressed as the nitrate ion.⁽¹⁾

LD₅₀ (rabbit, oral): 1.9 g/kg⁽²⁾

LD₅₀ (rat, oral): 3.75 g/kg

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of the material handled. Contact with other materials may cause fire. Thermal decomposition produces highly toxic fumes. Avoid creating and inhaling dust. Protective eye goggles, clothing, and respiratory equipment should be worn.