

Ethanol for Disinfection

Alcohol for Disinfection

消毒用エタノール

Ethanol for Disinfection contains not less than 76.9 vol% and not more than 81.4 vol% (by specific gravity) of ethanol (C₂H₆O: 46.07) at 15°C.

Method of preparation

Ethanol	830 mL
Purified Water	a sufficient quantity
To make 1000 mL	

Prepare by mixing the above ingredients.

Description Ethanol for Disinfection is a colorless, clear liquid. It has a characteristic odor and a burning taste.

It is miscible with water.

It burns with a light blue flame on ignition.

It is volatile.

Identification Proceed as directed in the Identification under Ethanol.

Specific gravity d_{15}^{15} : 0.860 – 0.873

Purity (1) Clarity of solution—Proceed as directed in the Purity (1) under Ethanol.

(2) Acid or alkali—Proceed as directed in the Purity (2) under Ethanol.

(3) Chloride—Proceed as directed in the Purity (3) under Ethanol.

(4) Heavy metals—Proceed as directed in the Purity (4) under Ethanol.

(5) Fusel oil constituents—Proceed as directed in the Purity (5) under Ethanol.

(6) Aldehyde and other foreign reducing substances—Proceed as directed in the Purity (6) under Ethanol.

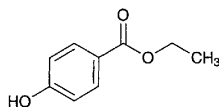
(7) Residue on evaporation—Proceed as directed in the Purity (8) under Ethanol.

Containers and storage Containers—Tight containers.

Storage—Light-resistant, and remote from fire.

Ethyl Parahydroxybenzoate

パラオキシ安息香酸エチル



C₉H₁₀O₃: 166.17

Ethyl 4-hydroxybenzoate [120-47-8]

Ethyl Parahydroxybenzoate, when dried, contains not less than 99.0% of C₉H₁₀O₃.

Description Ethyl Parahydroxybenzoate occurs as colorless crystals or a white, crystalline powder. It is odorless and taste-

less, numbing the tongue.

It is freely soluble in ethanol (95), in acetone and in diethyl ether, sparingly soluble in hot water, and very slightly soluble in water.

Its saturated solution is slightly acidic.

Identification (1) Dissolve 0.25 g of Ethyl Parahydroxybenzoate in 5 mL of dilute ethanol, and add 1 drop of iron (III) chloride TS: a red-purple color develops.

(2) Boil 0.5 g of Ethyl Parahydroxybenzoate with 10 mL of sodium hydroxide TS for 30 minutes, allowing the solution to evaporate to about 5 mL. After cooling, acidify with dilute sulfuric acid, collect the precipitate formed, wash thoroughly with a small amount of water, and dry in a desiccator (silica gel): the precipitate melts between 213°C and 217°C.

(3) To 0.05 g of Ethyl Parahydroxybenzoate add 2 drops of acetic acid (31) and 5 drops of sulfuric acid, and heat the mixture for 5 minutes: the odor of ethyl acetate is perceptible.

Melting point 116 – 118°C

Purity (1) Chloride—Heat 2.0 g of Ethyl Parahydroxybenzoate with 50 mL of water, allow to stand in ice water for 1 hour with occasional shaking, add water to make 100 mL, and filter. Perform the test with 25 mL of the filtrate. Prepare the control solution with 0.50 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.035%).

(2) Sulfate—Perform the test with 40 mL of the filtrate obtained in Purity (1). Prepare the control solution with 0.40 mL of 0.005 mol/L sulfuric acid VS (not more than 0.024%).

(3) Heavy metals—Dissolve 1.0 g of Ethyl Parahydroxybenzoate in 25 mL of acetone, add 2 mL of dilute acetic acid and water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution as follows: to 2.0 mL of Standard Lead Solution add 25 mL of acetone, 2 mL of dilute acetic acid, and water to make 50 mL (not more than 20 ppm).

(4) Parahydroxybenzoic acid and salicylic acid—Dissolve 0.5 g of Ethyl Parahydroxybenzoate in 30 mL of diethyl ether, shake with 20 mL of a solution of sodium hydrogen carbonate (1 in 100), wash the separated aqueous layer with two 20-mL portions of diethyl ether, shake the aqueous layer with 5 mL of dilute sulfuric acid and 30 mL of diethyl ether, and allow to stand. Shake gently the separated diethyl ether layer with 10 mL of water, remove the aqueous layer after allowing the mixture to stand, filter the diethyl ether solution, wash the vessel and the filter paper with a small amount of diethyl ether, evaporate the diethyl ether from the combined filtrate and washings on a water bath, and dry the residue in a desiccator (silica gel) to constant mass: the mass of the residue is not more than 5.0 mg. Warm the residue with 5 mL of water, filter, and to the filtrate add 2 to 3 drops of dilute iron (III) chloride TS: no purple color develops.

(5) Readily carbonizable substances—Perform the test with 0.50 g of Ethyl Parahydroxybenzoate. The solution has no more color than Matching Fluid D.

Loss on drying Not more than 0.5% (2 g, silica gel, 3 hours).

Residue on ignition Not more than 0.10% (1 g).

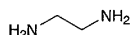
Assay Weigh accurately about 2 g of Ethyl Parahydroxybenzoate, previously dried, add exactly 40 mL of 1 mol/L sodium hydroxide VS, and boil for 30 minutes. Cool, and titrate the excess sodium hydroxide with 0.5 mol/L sulfuric acid VS until the solution shows the same color as that of phosphate buffer solution, pH 6.5, to which the same indicator has been added. (indicator: 5 drops of bromothymol blue TS). Perform a blank determination.

Each mL of 1 mol/L sodium hydroxide VS
= 166.18 mg of $C_9H_{10}O_3$

Containers and storage Containers—Well-closed containers.

Ethylenediamine

エチレンジアミン



$C_2H_8N_2$: 60.10
Ethane-1,2-diamine [107-15-3]

Ethylenediamine contains not less than 97.0% of $C_2H_8N_2$.

Description Ethylenediamine is a clear, colorless to pale yellow liquid. It has an ammonia-like odor.

It is miscible with water, with ethanol (95) and with diethyl ether.

It has a caustic nature and an irritating property.

It is gradually affected by air.

Specific gravity d_{20}^{20} : about 0.898

Identification (1) A solution of Ethylenediamine (1 in 500) is alkaline.

(2) To 2 mL of copper (II) sulfate TS add 2 drops of Ethylenediamine: a blue-purple color develops.

(3) To 0.04 g of Ethylenediamine add 6 drops of benzoyl chloride and 2 mL of a solution of sodium hydroxide (1 in 10), warm for 2 to 3 minutes with occasional shaking, collect the white precipitate formed, and wash with water. Dissolve the precipitate in 8 mL of ethanol (95) by warming, promptly add 8 mL of water, cool, filter the crystals, wash with water, and dry at 105°C for 1 hour: it melts between 247°C and 251°C.

Purity (1) Heavy metals—Place 1.0 g of Ethylenediamine in a porcelain crucible, evaporate to dryness on a water bath, cover loosely, ignite at a low temperature until charred, proceed according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(2) Residue on evaporation—Pipet 5 mL of Ethylenediamine, heat on a water bath to dryness, and dry to constant mass at 105°C: the mass of the residue does not exceed 3.0 mg.

Distilling range 114 – 119°C, not less than 95 vol%.

Assay Weigh accurately about 0.7 g of Ethylenediamine in a glass-stoppered conical flask, add 50 mL of water, and titrate with 1 mol/L hydrochloric acid VS (indicator: 3 drops

of bromophenol blue TS).

Each mL of 1 mol/L hydrochloric acid VS
= 30.049 mg of $C_2H_8N_2$

Containers and storage Containers—Tight containers.
Storage—Light-resistant, and almost well-filled.

Eucalyptus Oil

Oleum Eucalypti

ユーカリ油

Eucalyptus Oil is the essential oil distilled with steam from the leaves of *Eucalyptus globulus* Labillardière or allied plants (*Myrtaceae*).

Description Eucalyptus Oil is a clear, colorless or pale yellow liquid. It has a characteristic, aromatic odor and a pungent taste.

It is neutral.

Identification Shake 1 mL of Eucalyptus Oil vigorously with 1 mL of phosphoric acid, and allow to stand: the solution congeals within 30 minutes.

Refractive index n_D^{20} : 1.458 – 1.470

Specific gravity d_{20}^{20} : 0.907 – 0.927

Purity (1) Clarity of solution—Mix 1.0 mL of Eucalyptus Oil with 5 mL of diluted ethanol (7 in 10): the solution is clear.

(2) Heavy metals—Proceed with 1.0 mL of Eucalyptus Oil according to Method 2, and perform the test. Prepare the control solution with 4.0 mL of Standard Lead Solution (not more than 40 ppm).

Assay Weigh accurately about 0.1 g of Eucalyptus Oil, and dissolve in hexane to make exactly 25 mL. Pipet 5 mL of this solution, add exactly 5 mL of the internal standard solution, then add hexane to make 100 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.1 g of cineol for assay, proceed as directed in the sample solution, and use this solution as the standard solution. Perform the test with 2 μ L each of the sample solution and the standard solution as directed under the Gas Chromatography according to the following conditions. Calculate the ratios, Q_T and Q_S , of the peak area of cineol to that of the internal standard of each solutions, respectively.

$$\begin{aligned} &\text{Amount (mg) of cineol (C}_{10}\text{H}_{18}\text{O)} \\ &= \text{amount (mg) of cineol for assay} \\ &\quad \times \frac{Q_T}{Q_S} \end{aligned}$$

Internal standard solution—A solution of anisol in hexane (1 in 250).

Operating conditions—

Detector: A hydrogen flame-ionization detector.

Column: A glass column about 3 mm in inside diameter and about 5 m in length, having alkylene glycol phthalate ester for gas chromatography coated at the ratio of 10% on silanized siliceous earth for gas chromatography (150 to 180 μ m in particle diameter).