

Table II: Minimum inhibitory concentrations (MIC) of cetrimide.

Microorganism	MIC ($\mu\text{g}/\text{mL}$)
<i>Escherichia coli</i>	30
<i>Pseudomonas aeruginosa</i>	300
<i>Staphylococcus aureus</i>	10

Critical micelle concentration: $\approx 0.01\%$

Melting point: 232–247°C

Moisture content: at 40–50% relative humidity and 20°C, cetrimide absorbs sufficient moisture to cause caking and retard flow properties.

Partition coefficients:

Liquid paraffin : water = < 1

Vegetable oil : water = < 1

Solubility: freely soluble in chloroform, ethanol (95%), and water; practically insoluble in ether. A 2% w/v aqueous solution foams strongly on shaking.

11 Stability and Storage Conditions

Cetrimide is chemically stable in the dry state, and also in aqueous solution at ambient temperatures. Aqueous solutions may be sterilized by autoclaving. Water containing metal ions and organic matter may reduce the antimicrobial activity of cetrimide.

The bulk material should be stored in a well-closed container in a cool, dry place.

12 Incompatibilities

Incompatible with soaps, anionic surfactants, high concentrations of nonionic surfactants, bentonite, iodine, phenylmercuric nitrate, alkali hydroxides, and acid dyes. Aqueous solutions react with metals.

13 Method of Manufacture

Cetrimide is prepared by the condensation of suitable alkyl bromides and trimethylamine.

14 Safety

Most adverse effects reported relate to the therapeutic use of cetrimide. If ingested orally, cetrimide and other quaternary ammonium compounds can cause nausea, vomiting, muscle paralysis, CNS depression, and hypotension; concentrated solutions may cause esophageal damage and necrosis. The fatal oral human dose is estimated to be 1.0–3.0 g.⁽¹⁾

At the concentrations used topically, solutions do not generally cause irritation, although concentrated solutions have occasionally been reported to cause burns. Cases of hypersensitivity have been reported following repeated application.⁽²⁾

Adverse effects that have been reported following irrigation of hydatid cysts with cetrimide solution include chemical peritonitis,⁽³⁾ methemoglobinemia with cyanosis,⁽⁴⁾ and metabolic disorders.⁽⁵⁾

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Cetrimide powder and concentrated cetrimide solutions are irritant; avoid inhala-

tion, ingestion, and skin and eye contact. Eye protection, gloves, and a respirator are recommended.⁽⁶⁾

16 Regulatory Status

Included in nonparenteral medicines licensed in the UK.

17 Related Substances

Dodecyltrimethylammonium bromide; hexadecyltrimethylammonium bromide; trimethyltetradecylammonium bromide.

Dodecyltrimethylammonium bromide

Empirical formula: $\text{C}_{15}\text{H}_{34}\text{BrN}$

Molecular weight: 308.35

CAS number: [1119-94-4]

Synonyms: DTAB; *N*-lauryl-*N,N,N*-trimethylammonium bromide; *N,N,N*-trimethyldodecylammonium bromide.

Safety:

LD₅₀ (mouse, IV): 5.2 mg/kg⁽⁷⁾

LD₅₀ (rat, IV): 6.8 mg/kg

Hexadecyltrimethylammonium bromide

Empirical formula: $\text{C}_{19}\text{H}_{42}\text{BrN}$

Molecular weight: 364.48

CAS number: [57-09-0]

Synonyms: cetrimide BP 1953; cetrimonium bromide; cetyltrimethylammonium bromide; CTAB; *N,N,N*-trimethylhexadecylammonium bromide.

Appearance: a white to creamy-white, voluminous, free-flowing powder, with a characteristic faint odor and bitter, soapy taste.

Melting point: 237–243°C

Safety:

LD₅₀ (guinea pig, SC): 100 mg/kg⁽⁷⁾

LD₅₀ (mouse, IP): 106 mg/kg

LD₅₀ (mouse, IV): 32 mg/kg

LD₅₀ (rabbit, IP): 125 mg/kg

LD₅₀ (rabbit, SC): 125 mg/kg

LD₅₀ (rat, IV): 44 mg/kg

LD₅₀ (rat, oral): 410 mg/kg

Solubility: freely soluble in ethanol (95%); soluble 1 in 10 parts of water.

Comments: the original cetrimide BP 1953 consisted largely of hexadecyltrimethylammonium bromide, with smaller amounts of analogous alkyltrimethylammonium bromides. It contained a considerable proportion of inorganic salts, chiefly sodium bromide, and was less soluble than the present product.

Trimethyltetradecylammonium bromide

Empirical formula: $\text{C}_{17}\text{H}_{38}\text{BrN}$

Molecular weight: 336.40

CAS number: [1119-97-7]

Synonyms: myristyltrimethylammonium bromide; tetradecyltrimethylammonium bromide; *N,N,N*-trimethyl-1-tetradecanaminium bromide.

Safety:

LD₅₀ (mouse, IV): 12 mg/kg⁽⁷⁾

LD₅₀ (rat, IV): 15 mg/kg

18 Comments

As a precaution against contamination with *Pseudomonas* species resistant to cetrimide, stock solutions may be further

protected by adding at least 7% v/v ethanol or 4% v/v propan-2-ol.

The EINECS number for cetrimide is 214-291-9.

19 Specific References

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20 General References

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21 Author

SC Owen.

22 Date of Revision

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