Edetic Acid

1. Nonproprietary Names

USPNF: Edetic acid

2. Synonyms

Edathamil; EDTA; ethylenediaminetetraacetic acid; (ethylenedinitrilo)tetraacetic acid; *Questric acid 5286*; *Sequestrene AA*; *Versene Acid.*

3. Chemical Name and CAS Registry Numbers

N,*N*′-1,2-Ethanediylbis[*N*-(carboxymethyl)glycine]
[60-00-4]

4. Empirical Formula and Molecular Weight

$C_{10}H_{16}N_2O_8$ 292.24

5. Structural Formula

$(HOOCCH_2)_2NCH_2CH_2N(CH_2COOH)_2$

6. Functional Category

Chelating agent; therapeutic agent.

7. Applications in Pharmaceutical Formulation or Technology

Edetic acid and edetate salts are used in pharmaceutical formulations, cosmetics and foods as chelating agents; that is, they form stable water-soluble complexes (chelates) with alkaline earth and heavy metal ions. The chelated form has few of the properties of the free ion, and for this reason chelating agents are often described as 'removing' ions from solution; this process is also called sequestering. The stability of the metal-edetate complex depends on the metal ion involved and also on the pH. The calcium chelate is relatively weak and will preferentially chelate heavy metals, such as iron, copper and lead, with the release of calcium ions. For this reason, edetate calcium disodium is used therapeutically in cases of lead poisoning, *see also* Section 19.

Edetic acid and edetates are primarily used as antioxidant synergists by sequestering trace amounts of metal ions, particularly copper, iron and manganese, which might otherwise catalyze autoxidation reactions. Edetic acid and edetates may be used alone or in combination with true antioxidants, the usual concentration employed being in the range 0.005-0.1% w/v. Edetates have been used to stabilize: ascorbic acid; corticosteroids; epinephrine; folic acid; formaldehyde; gums and resins; hyaluronidase; hydrogen peroxide; oxytetracycline; penicillin; salicylic acid and unsaturated fatty acids. Essential oils may be washed with a 2% w/v solution of edetate to remove trace metal impurities.

Edetic acid and edetates possess some antimicrobial activity but are most frequently used in combination with other antimicrobial preservatives due to their synergistic effects. Many solutions used for the cleaning, storage and wetting of contact lenses thus contain disodium edetate. Typically, edetic acid and edetates are used in concentrations of 0.01-0.1% w/v as antimicrobial preservative synergists, *see* Section 10.

Edetic acid and disodium edetate may also be used as water softeners since they will chelate the calcium and magnesium ions present in hard water; edetate calcium disodium is not effective. Many cosmetic and toiletry products, e.g. soaps, contain edetic acid as a water softener.

Disodium edetate is also used as an anticoagulant since it will chelate calcium and prevent the coagulation of blood *in vitro*. Concentrations of 0.1% w/v are used in small volumes for hematological testing and 0.3% w/v in transfusions.

8. Description

Edetic acid occurs as a white crystalline powder.

9. Pharmacopeial Specifications

Test	USPNF XVII
Identification	+
Residue on ignition	⩽ 0.2%
Heavy metals	⩽ 0.003%
Nitrilotriacetic acid	⩽ 0.3%
Iron	⩽ 0.005%
Assay	98.0-100.5%

10. Typical Properties

Acidity/alkalinity:
pH = 2.2 for a 0.2% w/v aqueous solution.

Antimicrobial activity: edetic acid has some antimicrobial activity against Gram-negative microorganisms, *Pseudomonas aeruginosa*, some yeasts and fungi, although this activity is insufficient for edetic acid to be used effectively as an antimicrobial preservative on its own.[1,2] However, when used with other antimicrobial preservatives edetic acid demonstrates a marked synergistic effect in its antimicrobial activity. Edetic acid and edetates are therefore frequently used in combination with such preservatives as: benzalkonium chloride; bronopol; cetrimide; imidurea; parabens and phenols, especially chloroxylenol. Typically, edetic acid is used at a concentration of 0.1-0.15% w/v. In the presence of some divalent metal ions, such as Ca^{2+} or Mg^{2+}, the synergistic effect may be reduced or lost altogether. The addition of disodium edetate to phenylmercuric nitrate[3] and thimerosal [3, 4] has also been reported to reduce the antimicrobial efficacy of the preservative. Edetic acid and iodine form a colorless addition compound which is bactericidal.

Dissociation constant:
pK_{a1} = 2.00;
pK_{a2} = 2.67;
pK_{a3} = 6.16;
pK_{a4} = 10.26.

Melting point: melts above 220°C, with decomposition.

Solubility: soluble in solutions of alkali hydroxides; soluble 1 in 500 of water.

11. Stability and Storage Conditions

Although edetic acid is fairly stable in the solid state, edetate salts are more stable than the free acid, which decarboxylates if heated above 150°C. Disodium edetate dihydrate loses water of crystallization when heated to 120°C. Edetate calcium disodium is slightly hygroscopic and should be protected from moisture.

Aqueous solutions of edetic acid or edetate salts may be sterilized by autoclaving, and should be stored in an alkali-free container.

Edetic acid and edetates should be stored in well-closed containers in a cool, dry, place.

12. Incompatibilities

Edetic acid and edetates are incompatible with strong oxidizing agents, strong bases and polyvalent metal ions such as copper, nickel and copper alloy.

Edetic acid and disodium edetate behave as weak acids, displacing carbon dioxide from carbonates and reacting with metals to form hydrogen.

Other incompatibilities include the inactivation of certain types of insulin due to the chelation of zinc, and the chelation of trace metals in TPN solutions following the addition of TPN additives stabilized with disodium edetate. Calcium disodium edetate has also been reported to be incompatible with amphotericin and with hydralazine hydrochloride in infusion fluids.

13. Method of Manufacture

Edetic acid may be prepared by the condensation of ethylenediamine with sodium monochloroacetate in the presence of sodium carbonate. An aqueous solution of the reactants is heated to about 90°C for ten hours, then cooled, and hydrochloric acid added to precipitate the edetic acid.

Edetic acid may also be prepared by the reaction of ethylenediamine with hydrogen cyanide and formaldehyde with subsequent hydrolysis of the tetranitrile, or under alkaline conditions with continuous extraction of ammonia.

See Section 18 for information on the preparation of edetate salts.

14. Safety

Edetic acid and edetates are widely used in topical, oral and parenteral pharmaceutical formulations. They are also extensively used in cosmetics and food products.

Edetic acid is generally regarded as an essentially nontoxic and nonirritant material although it has been associated with dose-related bronchoconstriction when used as a preservative in nebulizer solutions. It has therefore been recommended that nebulizer solutions for bronchodilation should not contain edetic acid.[5]

Edetates, particularly disodium edetate and edetate calcium disodium, are used in a greater number and variety of pharmaceutical formulations than the free acid. Both disodium edetate and edetate calcium disodium are poorly absorbed from the gastrointestinal tract and are associated with few adverse effects when used as excipients in pharmaceutical formulations.

Disodium edetate, trisodium edetate and edetic acid readily chelate calcium and can, in large doses, cause calcium depletion (hypocalcemia) if used over an extended period or if administered too rapidly by intravenous infusion. If used in preparations for the mouth, they can also leach calcium from the teeth. In contrast, edetate calcium disodium does not chelate calcium.

Edetate calcium disodium is nephrotoxic and should be used with caution in patients with renal impairment. Disodium edetate should similarly be used with caution in patients with renal impairment, tuberculosis and impaired cardiac function.

The WHO has set an estimated acceptable daily intake for disodium edetate in foodstuffs at up to 2.5 mg/kg body-weight.[6]

See also Section 19.

LD_{50} (mouse, IP): 0.25 g/kg[7]
LD_{50} (mouse, oral): 0.03 g/kg
LD_{50} (rat, IP): 0.397 g/kg

15. Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Edetic acid and edetates are mildly irritant to the skin, eyes and mucous membranes. Ingestion, inhalation and contact with the skin and eyes should therefore be avoided. Eye protection, gloves and a dust mask are recommended.

16. Regulatory Status

Included in the FDA Inactive Ingredients Guide (otic, rectal and topical preparations). Included in nonparenteral medicines licensed in the UK.

See also Section 18.

17. Pharmacopeias

Rom and USPNF.

18. Related Substances

Dipotassium edetate; disodium edetate; edetate calcium disodium; sodium edetate; trisodium edetate.

Dipotassium edetate: $C_{10}H_{14}K_2N_2O_8$
Molecular weight: 368.46
CAS number: [2001-94-7]
Synonyms: dipotassium edathamil; dipotassium ethylenediaminetetraacetate; edathamil dipotassium; edetate dipotassium; edetic acid dipotassium salt; EDTA dipotassium; *N,N'*-1,2-ethanediylbis[*N*-(carboxymethyl)glycine] dipotassium salt; ethylenebis(iminodiacetic acid) dipotassium salt; ethylenediaminetetraacetic acid dipotassium salt; (ethylenedinitrilo)tetraacetic acid dipotassium salt; tetracemate dipotassium.
Appearance: white crystalline powder.

Disodium edetate: $C_{10}H_{14}N_2Na_2O_8$
Molecular weight: 336.21
CAS number:
[139-33-3] for the anhydrous material;
[6381-92-6] for the dihydrate.
Synonyms: disodium edathamil; disodium ethylenediaminetetraacetate; edathamil disodium; edetate disodium; edetic acid disodium salt; EDTA disodium; *N,N'*-1,2-ethanediylbis[*N*-(carboxymethyl)glycine] disodium salt; ethylenebis(iminodiacetic acid) disodium salt; ethylenediaminetetraacetic acid disodium salt; (ethylenedinitrilo)tetraacetic acid disodium salt; *Questal Di*; *Sequestrene NA2*; tetracemate disodium; *Versene disodium*.
Appearance: odorless white crystalline powder with a slightly acid taste.
Pharmacopeias: Belg, Br, Eur, Fr, Gr, Hung, Ind, It, Jpn, Mex, Neth, Nord, Port, Swiss, Turk, US and Yug.
Acidity/alkalinity: pH = 4.3-4.7 for a 1% w/v solution in carbon dioxide free water.
Freezing point depression:
0.14°C (1% w/v aqueous solution)
Melting point:
decomposition at 252°C for the dihydrate.
Refractive index:
1.335 for a 1% w/v aqueous solution.
Solubility: practically insoluble in chloroform and ether; slightly soluble in ethanol (95%); soluble 1 in 11 of water.
Specific gravity:
1.004 for a 1% w/v aqueous solution.
Viscosity (kinematic): 1.03 mm^2/s (1 cSt) for a 1% w/v aqueous solution.

Method of manufacture: disodium edetate may be prepared by the reaction of edetic acid and sodium hydroxide.
Safety: *see also* Section 14.
LD_{50} (mouse, IP): 0.26 g/kg[7]
LD_{50} (mouse, IV): 0.056 g/kg
LD_{50} (mouse, oral): 2.05 g/kg
LD_{50} (rabbit, IV): 0.047 g/kg
LD_{50} (rabbit, oral): 2.3 g/kg
LD_{50} (rat, oral): 2 g/kg
LD_{50} (rat, SC): 3.735 g/kg
Regulatory status: GRAS listed. Included in the FDA Inactive Ingredients Guide (inhalations, injections, ophthalmic preparations, oral capsules, solutions, suspensions, syrups and tablets, rectal, topical and vaginal preparations). Included in nonparenteral and parenteral medicines licensed in the UK.
Comments: in pharmaceutical formulations disodium edetate is used as a chelating agent typically at concentrations between 0.005-0.1% w/v.

Edetate calcium disodium: $C_{10}H_{12}CaN_2Na_2O_8$
Molecular weight: 374.28
CAS number:
[62-33-9] for the anhydrous material;
[23411-34-9] for the dihydrate.
Synonyms: 385; calcium disodium edetate; calcium disodium ethylenediaminetetraacetate; calcium disodium (ethylenedinitrilo)tetraacetate; edathamil calcium disodium; edetic acid calcium disodium salt; [[*N*,*N*′-1,2-ethanediylbis[*N*-(carboxymethyl)glycinat o]](4-)-*N*,*N*′,*O*,*O*′,O^N,-$O^{N'}$]calciate(2-)disodium; EDTA calcium; ethylenediaminetetraacetic acid calcium disodium chelate; [(ethylenedinitrilo)tetraacetato] calciate(2-) disodium; sodium calciumedetate; *Versene CA*.
Appearance: white or creamy-white colored, slightly hygroscopic, crystalline powder or granules; odorless, or with a slight odor; tasteless, or with a faint saline taste.
Pharmacopeias: Belg, Br, Cz, Egypt, Eur, Fr, Gr, It, Mex, Neth, Nord, Port, Swiss, Turk, US and Yug. Also in BP Vet. Some pharmacopeias specify that edetate calcium disodium is the dihydrate, others that it is the anhydrous material. The USP XXII specifies that edetate calcium disodium is a mixture of the dihydrate and trihydrate but that the dihydrate predominates.
Acidity/alkalinity:
pH = 4-5 for a 1% w/v aqueous solution.
Density (bulk): 0.69 g/cm^3
Solubility: practically insoluble in chloroform, ether and other organic solvents; very slightly soluble in ethanol (95%); soluble 1 in 2 of water.
Method of manufacture: edetate calcium disodium may be prepared by the addition of calcium carbonate to a solution of disodium edetate.
Safety: *see also* Section 14.
LD_{50} (dog, oral): 12 g/kg[7]
LD_{50} (mouse, IP): 4.5 g/kg
LD_{50} (mouse, oral): 10 g/kg
LD_{50} (rabbit, IP): 6 g/kg
LD_{50} (rabbit, oral): 7 g/kg
LD_{50} (rat, IP): 3.85 g/kg
LD_{50} (rat, IV): 3.0 g/kg
LD_{50} (rat, oral): 10 g/kg
Regulatory status: GRAS listed. Accepted for use as a food additive in the UK. Included in the FDA Inactive Ingredients Guide (injections, oral capsules, solutions, suspensions, syrups and tablets).
Comments: used in pharmaceutical formulations as a chelating agent in concentrations between 0.01-0.1% w/v. Usually edetate calcium disodium is used in pharmaceutical formulations in preference to disodium edetate or sodium edetate to prevent calcium depletion occurring in the body. In food products, edetate calcium disodium may also be used in flavors and as a color retention agent. Edetate calcium disodium occurs as the dihydrate, trihydrate and anhydrous material.

Sodium edetate: $C_{10}H_{12}N_2Na_4O_8$
Molecular weight: 380.20
CAS number: [64-02-8]
Synonyms: edetate sodium; edetic acid tetrasodium salt; EDTA tetrasodium; *N*,*N*′-1,2-ethanediylbis[*N*-(carboxymethyl)glycine] tetrasodium salt; ethylenebis(iminodiacetic acid) tetrasodium salt; ethylenediaminetetraacetic acid tetrasodium salt; (ethylenedinitrilo)tetraacetic acid tetrasodium salt; *Sequestrene NA4*; tetracemate tetrasodium; tetracemin; tetrasodium edetate; tetrasodium ethylenebis(iminodiacetate); tetrasodium ethylenediaminetetraacetate; *Versene*.
Appearance: white crystalline powder.
Acidity/alkalinity:
pH = 11.3 for a 1% w/v aqueous solution.
Melting point: > 300°C
Solubility: soluble 1 in 1 of water.
Safety: *see also* Section 14.
LD_{50} (mouse, IP): 0.33 g/kg[7]
Regulatory status: included in the FDA Inactive Ingredients Guide (inhalations, injections, ophthalmic preparations, oral capsules and tablets, and topical preparations).
Comments: sodium edetate reacts with most divalent and trivalent metallic ions to form soluble metal chelates and is used in pharmaceutical formulations in concentrations between 0.01-0.1% w/v.

Trisodium edetate: $C_{10}H_{13}N_2Na_3O_8$
Molecular weight: 358.20
CAS number: [150-38-9]
Synonyms: edetate trisodium; edetic acid trisodium salt; EDTA trisodium; *N*,*N*′-1,2-ethanediylbis[*N*-(carboxymethyl)glycine] trisodium salt; ethylenediaminetetraacetic acid trisodium salt; (ethylenedinitrilo)tetraacetic acid trisodium salt; *Sequestrene NA3*; trisodium ethylenediaminetetraacetate; *Versene-9*.
Appearance: white crystalline powder.
Acidity/alkalinity:
pH = 9.3 for a 1% w/v aqueous solution.
Melting point: > 300°C
Method of manufacture: trisodium edetate may be prepared by adding a solution of sodium hydroxide to disodium edetate.
Safety: *see also* Section 14.
LD_{50} (mouse, IP): 0.3 g/kg[7]
LD_{50} (mouse, oral): 2.15 g/kg
LD_{50} (rat, oral): 2.15 g/kg
Regulatory status: included in the FDA Inactive Ingredients Guide (topical preparations).
Comments: more soluble in water than either the disodium salt or the free acid. Trisodium edetate also occurs as the monohydrate and is used in pharmaceutical formulations as a chelating agent.
Other salts of edetic acid which are commercially available include diammonium, dimagnesium, dipotassium, ferric sodium and magnesium disodium edetates.

19. Comments

Therapeutically, a dose of 50 mg/kg body-weight of disodium edetate, as a slow infusion over a 24 hour period, with a maximum daily dose of 3 g, has been used as a treatment for hypercalcemia. For the treatment of lead poisoning, a dose of

60-80 mg/kg of edetate calcium disodium, as a slow infusion in two daily doses, for 5 days, has been used.

20. Specific References

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7. Sweet DV, editor. Registry of toxic effects of chemical substances. Cincinnati: US Department of Health, 1987.

21. General References

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22. Authors

UK: RS Cook; N Yussuf.

Sodium Metabisulfite

1. Nonproprietary Names

BP: Sodium metabisulphite
PhEur: Natrii metabisulfis
USPNF: Sodium metabisulfite

2. Synonyms

Disodium disulfite; disodium pyrosulfite; disulfurous acid disodium salt; E223; sodium acid sulfite.

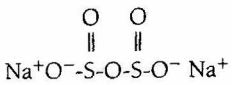
3. Chemical Name and CAS Registry Number

Sodium pyrosulfite [7681-57-4]

4. Empirical Formula Molecular Weight

$Na_2S_2O_5$ 190.1

5. Structural Formula



6. Functional Category

Antioxidant.

7. Applications in Pharmaceutical Formulation or Technology

Sodium metabisulfite is used as an antioxidant in oral, parenteral and topical pharmaceutical formulations. Primarily, sodium metabisulfite is used in acidic preparations; for alkaline preparations, sodium sulfite is usually preferred, *see* Sections 18 and 19. Sodium metabisulfite also has some antimicrobial activity, which is greatest at acid pH, and may be used as a preservative in oral preparations such as syrups.
In the food industry, and in wine production, sodium metabisulfite is similarly used as an antioxidant, antimicrobial preservative and anti-browning agent. However, at concentrations above about 500 ppm it imparts a noticeable flavor to preparations.
Sodium metabisulfite usually contains small amounts of sodium sulfite and sodium sulfate, *see* Section 18.

Use	Concentration (%)
Antioxidant	0.01-1.0

8. Description

Sodium metabisulfite occurs as colorless, prismatic crystals or as a white to creamy-white crystalline powder which has the odor of sulfur dioxide and an acidic, saline taste. Sodium metabisulfite crystallizes from water as a hydrate containing $7H_2O$.

9. Pharmacopeial Specifications

Test	PhEur 1993	USPNF XVII
Identification	+	+
Appearance of solution	+	—
pH (5% w/v solution)	3.5-5.0	—
Chloride	—	⩽ 0.05%
Thiosulfate	+	⩽ 0.05%
Arsenic	⩽ 5 ppm	⩽ 3 ppm
Heavy metals	⩽ 20 ppm	⩽ 0.002%
Iron	⩽ 20 ppm	⩽ 0.002%
Assay (as $Na_2S_2O_5$)	95-100.5%	—
Assay (as SO_2)	—	65-67.4%

10. Typical Properties

Acidity/alkalinity: pH = 3.5-5.0 for a 5% w/v aqueous solution at 20°C.
Melting point: sodium metabisulfite melts with decomposition at less than 150°C.
Osmolarity: a 1.38% w/v aqueous solution is iso-osmotic with serum.
Solubility:

Solvent	Solubility at 20°C Unless otherwise stated
Ethanol (95%)	slightly soluble
Glycerin	freely soluble
Water	1 in 1.9
	1 in 1.2 at 100°C

11. Stability and Storage Conditions

On exposure to air and moisture, sodium metabisulfite is slowly oxidized to sodium sulfate with disintegration of the crystals.[1] Addition of strong acids, to the solid, liberates sulfur dioxide.
In water, sodium metabisulfite is immediately converted to sodium (Na^+) and bisulfite (HSO_3^-) ions. Aqueous sodium metabisulfite solutions also decompose in air, especially on heating, and solutions which are to be sterilized by autoclaving should therefore be filled into containers in which the air has been replaced with an inert gas, such as nitrogen. The addition of dextrose to aqueous sodium metabisulfite solutions results in a decrease in the stability of the metabisulfite.[2]
The bulk material should be stored in a well-closed container, protected from light, in a cool, dry, place.

12. Incompatibilities

Sodium metabisulfite reacts with sympathomimetics and other drugs which are *ortho*- or *para*-hydroxybenzyl alcohol derivatives to form sulfonic acid derivatives possessing little or no pharmacological activity. The most important drugs subject to this inactivation are adrenaline and its derivatives.[3]
In addition, sodium metabisulfite is incompatible with chloramphenicol, due to a more complex reaction,[3] and inactivates cisplatin in solution;[4,5] it is also incompatible with phenylmercuric acetate when autoclaved in eye-drop preparations.[6]
Sodium metabisulfite may react with the rubber caps of multidose vials which should therefore be pre-treated with sodium metabisulfite solution.[7]

13. Method of Manufacture

Sodium metabisulfite is prepared by saturating a solution of sodium hydroxide with sulfur dioxide and allowing crystallization to occur; hydrogen is passed through the solution to

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