

Erythritol

1 Nonproprietary Names

BP: Erythritol

PhEur: Erythritol

USP–NF: Erythritol

2 Synonyms

Butane 1,2,3,4-tetrol; 1,2,3,4-butanetetrol; *C*Eridex*; E968; erythrit; erythrite; erythritolum; erythroglucin; erythrol; *meso*-erythritol; L(-)-threitol; paycite; phycite; phycitol; tetrahydroxybutane; *Zerose*.

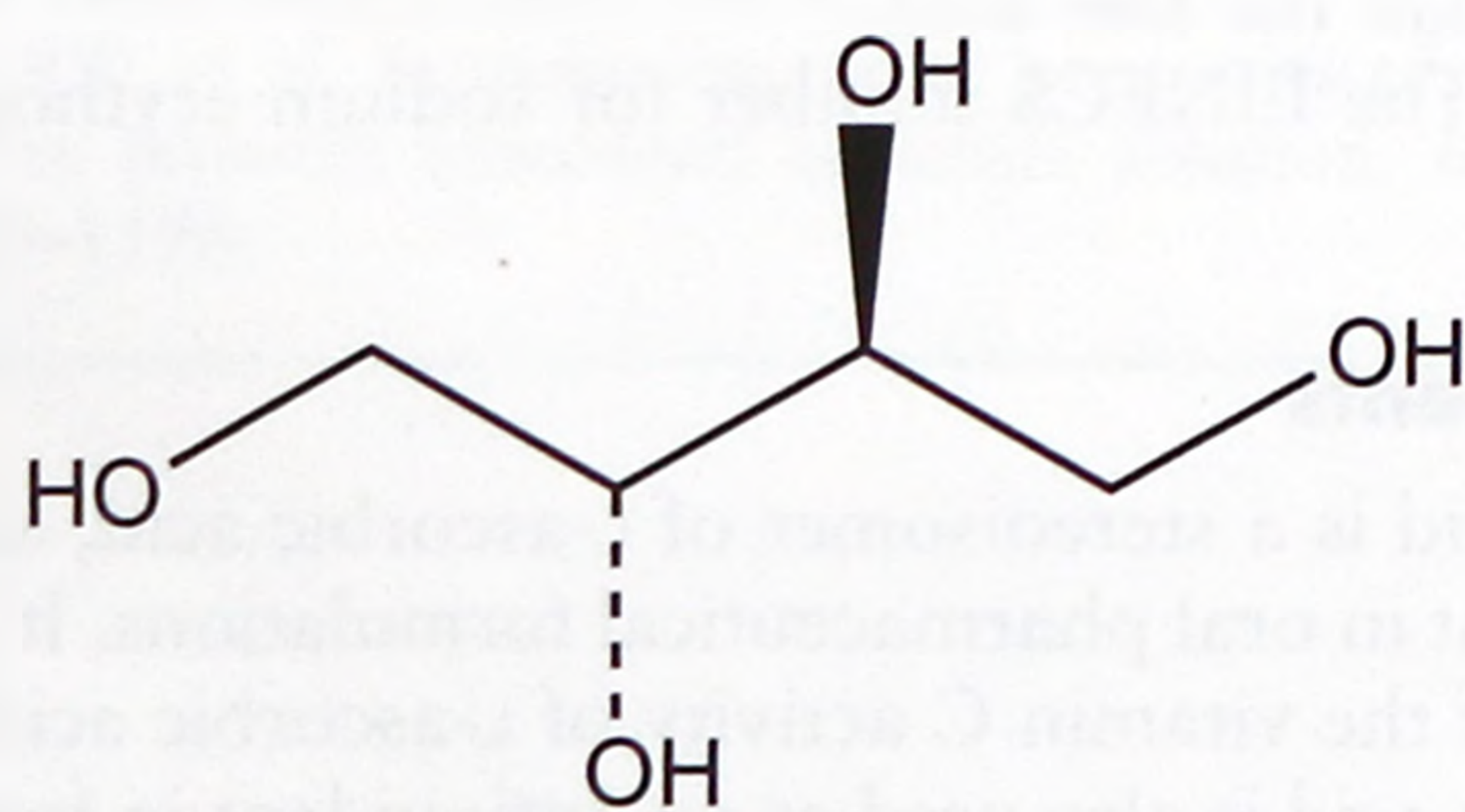
3 Chemical Name and CAS Registry Number

(2*R*,3*S*)-Butane 1,2,3,4-tetrol [149-32-6]

4 Empirical Formula and Molecular Weight

C₄H₁₀O₄ 122.12

5 Structural Formula



6 Functional Category

Sweetening agent; tablet and capsule diluent; taste-masking agent.

7 Applications in Pharmaceutical Formulation or Technology

Erythritol is a naturally occurring noncariogenic excipient used in a variety of pharmaceutical preparations, including in solid dosage forms as a tablet filler,⁽¹⁾ and in coatings.^(2,3) It has also been investigated for use in dry powder inhalers.^(4,5) It is also used in sugar-free lozenges,^(6,7) syrups, and medicated chewing gum.⁽⁶⁾

Erythritol can also be used as a diluent in wet granulation in combination with moisture-sensitive drugs.⁽⁸⁾ Erythritol demonstrates superior powder flow behavior and good stability because of its low hygroscopicity, making it a suitable carrier for actives in sachets and capsules, and as a diluent in direct compression tableting.⁽⁸⁾ In buccal applications, such as medicated chewing gums, it is used because of its high negative heat of solution which provides a strong cooling effect.⁽⁶⁾

Erythritol is also used as a noncaloric sweetener in syrups;⁽⁹⁾ it is used to provide sensorial profile-modifying properties with intense sweeteners; and it is also used to mask unwanted aftertastes.⁽¹⁰⁾

Erythritol is also used as a noncariogenic sweetener in toothpastes and mouthwash solutions.

See Table I.

8 Description

Erythritol is a sugar alcohol (polyol) that occurs as a white or almost white powder or granular or crystalline substance. It is pleasant tasting with a mild sweetness approximately 60–70% that of

sucrose. It also has a high negative heat of solution that provides a strong cooling effect.

Table I: Uses of erythritol.

Use	Concentration (%)
Tablet filler and binder	30.0–90.0
Taste masking in solutions	0.5–3.0
Oral care products	5.0–10.0

9 Pharmacopeial Specifications

See Table II. See also Section 18.

Table II: Pharmacopeial specifications for erythritol.

Test	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+
Melting point	119–122°C	119–123°C
Appearance of solution	+	–
Conductivity	≤ 20 μS/cm	≤ 20 μS/cm
Related substances	≤ 2.0%	≤ 2.0%
Lead	≤ 0.5 ppm	≤ 0.5 ppm
Water	≤ 0.5%	≤ 0.5%
Loss on drying	–	≤ 0.2%
Residue on ignition	–	≤ 0.1%
Microbial contamination	+	+
Bacterial endotoxins	+	–
Assay (anhydrous basis)	96.0–102.0%	96.0–102.0%

10 Typical Properties

Acidity/alkalinity pH = 5–7 at 25°C for a 5% w/v aqueous solution.

Boiling point 329–331°C

Caloric value 0.8 kJ/g

Density 1.45 g/cm³

Dissociation constant p*K*_a = 13.90 at 18°C⁽¹¹⁾

Glass transition temperature –42 to –46°C⁽¹²⁾

Heat of solution 23.3 kJ/mol⁽¹¹⁾

Hygroscopicity Erythritol is nonhygroscopic; it absorbs approximately 1% w/w of water at 95% relative humidity (RH).⁽⁸⁾

Melting point 121.5°C, with decomposition at 160°C.

Solubility Freely soluble in water; slightly soluble in ethanol (95%); practically insoluble in ether and fats.

Spectroscopy

NIR spectrum see Figure 1.

Viscosity (dynamic) 3 mPa·s (3 cP) at 60°C for a 30% w/w solution.

11 Stability and Storage Conditions

Erythritol has very good thermal and chemical stability. It is nonhygroscopic, and at 25°C does not significantly absorb additional water (<0.5%) up to a relative humidity (RH) of more than 90%.⁽⁸⁾ Erythritol resists decomposition both in acidic and alkaline media and remains stable for prolonged periods at pH 2–10.⁽¹³⁾

Store in a cool, dry place, away from sources of ignition. When stored for up to 4 years in ambient conditions (20°C, 50% RH) erythritol has been shown to be stable.⁽⁸⁾