

**17 Related Substances**

Aliphatic polyesters; sodium lactate.

**18 Comments**

Therapeutically, lactic acid is used in injections, in the form of lactate, as a source of bicarbonate for the treatment of metabolic acidosis; as a spermicidal agent; in pessaries for the treatment of leukorrhea; in infant feeds; and in topical formulations for the treatment of warts.

A specification for lactic acid is contained in the *Food Chemicals Codex* (FCC).<sup>(6)</sup>

The EINECS number for lactic acid is 200-018-0. The PubChem Compound ID (CID) for lactic acid includes 612, 107689 and 61503.

**19 Specific References**

- 1 Brophy MR, Deasy P. Biodegradable polyester polymers as drug carriers. In: Swarbrick J, Boylan JC, eds. *Encyclopedia of Pharmaceutical Technology*. 2. New York: Marcel Dekker, 1990: 1–25.
- 2 Kim IS, et al. Core-shell type polymeric nanoparticles composed of poly(L-lactic acid) and poly(N-isopropylacrylamide). *Int J Pharm* 2000; 211: 1–8.

- 3 Datta R, Henry M. Lactic acid: recent advances in products, processes and technologies - a review. *J Chem Technol Biotechnol* 2006; 81: 1119–1129.
- 4 FAO/WHO. Toxicological evaluation of certain food additives with a review of general principles and specifications. Seventeenth report of the FAO/WHO expert committee on food additives. *World Health Organ Tech Rep Ser* 1974; No. 539.
- 5 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 12th edn. New York: Wiley, 2012: 2696.
- 6 *Food Chemicals Codex*. [online] Bethesda, MD: United States Pharmacopeia. <http://publications.usp.org> (accessed 31 March 2017).

**20 General References**

Al-Shammary FJ et al. *Analytical Profiles of Drug Substances and Excipients*. 22. San Diego: Academic Press, 1993: 263–316.

**21 Author**

MG Lee.

**22 Date of Revision**

4 May 2017.

# Lactitol

**1 Nonproprietary Names**

BP: Lactitol Monohydrate

PhEur: Lactitol Monohydrate

USP–NF: Lactitol

**2 Synonyms**

E966; *Finlac DC*; β-galactosido-sorbitol; lactil; lactite; lactitolum monohydricum; lactobiosit; lactosit; *Lacty*.

**3 Chemical Name and CAS Registry Number**

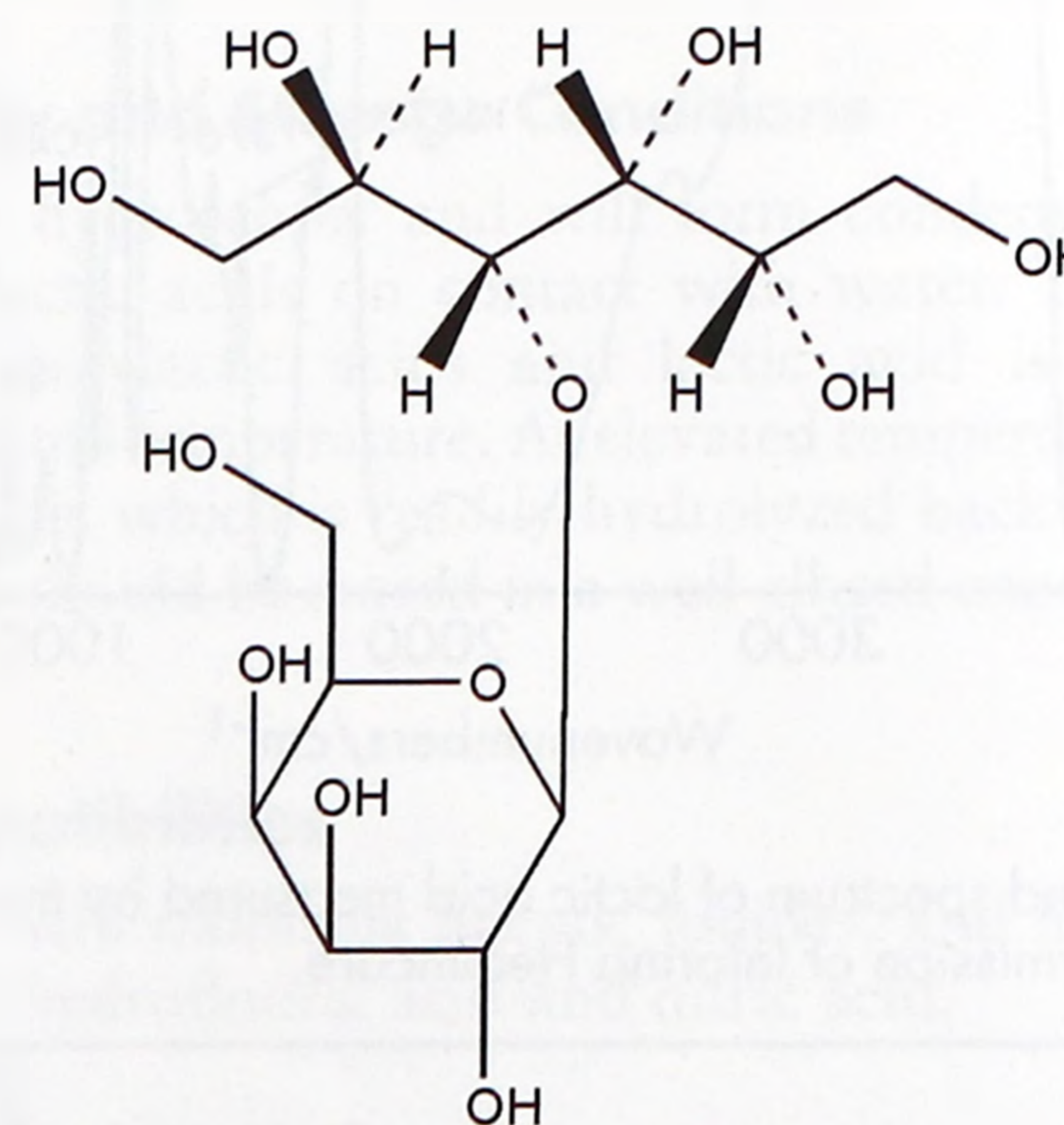
4-O-(β-D-Galactopyranosyl)-D-glucitol [585-86-4]

4-O-(β-D-Galactopyranosyl)-D-glucitol monohydrate [81025-04-9]

4-O-(β-D-Galactopyranosyl)-D-glucitol dihydrate [81025-03-8]

**4 Empirical Formula and Molecular Weight**

|                                  |                      |
|----------------------------------|----------------------|
| $C_{12}H_{24}O_{11}$             | 344.32 (anhydrous)   |
| $C_{12}H_{24}O_{11} \cdot H_2O$  | 362.34 (monohydrate) |
| $C_{12}H_{24}O_{11} \cdot 2H_2O$ | 380.35 (dihydrate)   |

**5 Structural Formula****6 Functional Category**

Direct compression excipient; sweetening agent; tablet and capsule diluent.

**7 Applications in Pharmaceutical Formulation or Technology**

Lactitol is used as a noncariogenic replacement for sucrose. It is also used in tablet formulations as a diluent in direct-compression processes.<sup>(1–4)</sup>

**8 Description**

Lactitol occurs as white orthorhombic crystals. It is odorless with a sweet taste that imparts a cooling sensation. It is available in powdered form and in a range of crystal sizes. The directly