Lactitol

1 Nonproprietary Names

BP: Lactitol monohydrate
PhEur: Lactitolum monohydricum
USPNF: Lactitol

2 Synonyms

E966; β-galactosido-sorbitol; *Finlac ACX*; *Finlac DC*; *Finlac MCX*; lactil; lactite; lactobiosit; lactosit; Lacty.

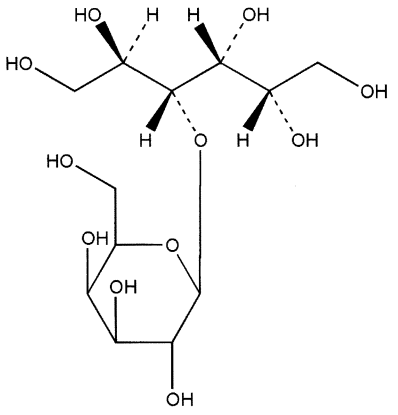
3 Chemical Name and CAS Registry Number

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

Empirical Formula	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

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 as a diluent in solid dosage forms.[1] A direct-compression form is available,[2] as is a direct-compression blend of lactose and lactitol. Lactitol is also used therapeutically in the treatment of hepatic encephalopathy and as a laxative; *see* Section 14.

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 compressible form is a water-granulated product of microcrystalline aggregates.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for lactitol.

Test	PhEur 2002	USPNF 20
Identification	+	+
Characters	+	—
Appearance of solution	+	—
Acidity or alkalinity	+	—
Specific optical rotation	+13.5° to +15.5°	—
Related substances	≤1.5%	≤1.5%
Reducing sugars	≤0.2%	≤0.2% as dextrose
Lead	≤0.5 ppm	—
Nickel	≤1 ppm	—
Water		
monohydrate	4.5–5.5%	4.5–5.5%
dihydrate	—	9.5–10.5%
anhydrous	—	≤0.5%
Microbial contamination	≤1000/g	—
Residue on ignition	≤0.1%	≤0.5%
Heavy metals	—	≤5 ppm
Organic volatile impurities	—	+
Assay	≥97.0%	98.0–101.0%

10 Typical Properties

Acidity–alkalinity: pH = 4.5–7.0 (10% w/v solution).
Density: 1.54 g/cm^3
Heat of solution: −54 J/g
Loss of water of crystallization: 145–185°C
Moisture content: 4.5–5.5% for the monohydrate; ≤0.5% for the anhydrous.
Osmolarity: a 7% w/v aqueous solution is isoosmotic with serum.
Refractive index:
n_D^{20} = 1.3485 (10% solution)
n_D^{20} = 1.3650 (20% solution)
n_D^{20} = 1.3827 (30% solution)
n_D^{20} = 1.4018 (40% solution)
n_D^{20} = 1.4228 (50% solution)
n_D^{20} = 1.4466 (60% solution)
Solubility: slightly soluble in ethanol and ether. Soluble 1 in 1.75 of water at 20°C; 1 in 1.61 at 30°C; 1 in 1.49 at 40°C; 1 in 1.39 at 50°C.
Specific rotation $[\alpha]_D^{20}$: +14.5° to +15°
Viscosity (dynamic):
1.3 mPa s (1.3 cP) for 10% solution at 20°C
1.9 mPa s (1.9 cP) for 20% solution at 20°C

3.4 mPa s (3.4 cP) for 30% solution at 20°C
6.9 mPa s (6.9 cP) for 40% solution at 20°C
18.9 mPa s (18.9 cP) for 50% solution at 20°C
80.0 mPa s (80.0 cP) for 60% solution at 20°C

11 Stability and Storage Conditions

Lactitol as the monohydrate is nonhygroscopic and is stable under humid conditions. It is stable to heat and does not take part in the Maillard reaction. In acidic solution, lactitol slowly hydrolyzes to sorbitol and galactose. Lactitol is very resistant to microbiological breakdown and fermentation. Store in a well-closed container. When the compound is stored in an unopened container at 25°C and 60% relative humidity, a shelf-life in excess of 3 years is appropriate.

12 Incompatibilities

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13 Method of Manufacture

Lactitol is produced by the catalytic hydrogenation of lactose.

14 Safety

Lactitol is regarded as a nontoxic and nonirritant substance. It is not fermented significantly in the mouth, and is not cariogenic.[3] It is not absorbed in the small intestine, but is broken down by microflora in the large intestine,[4] and is metabolized independently of insulin. In large doses it has a laxative effect; therapeutically, 10–20 g daily in a single oral dose is administered for this purpose.

LD_{50} (mouse, oral): >23 g/kg[5]
LD_{50} (rat, oral): 30 g/kg

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection is recommended.

16 Regulatory Status

GRAS listed. Accepted as a food additive in Europe.

17 Related Substances

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18 Comments

Finlac DC is a commercially available water-granulated directly compressible lactitol.[2]

Lactitol has a sweetening power about one-third that of sucrose. It does not promote dental caries and has a caloric value of 9.9 J/g (2.4 cal/g).

The EINECS number for lactitol is 209-566-5.

19 Specific References

1 Allen LV. Featured excipient: capsule and tablet diluents. *Int J Pharm Compound* 2000; **4**(4): 306–310, 324–325.
2 Armstrong NA. Direct compression characteristics of lactitol. *Pharm Technol Eur* 1998; **10**(2): 42–46.
3 Grenby TH, Philips A, Mistry M. Studies on the dental properties of lactitol compared with five other bulk sweeteners *in vitro*. *Caries Res* 1989; **23**: 315–319.
4 Grimble GK, Patil DH, Silk DBA. Assimilation of lactitol, an unabsorbed disaccharide in the normal human colon. *Gut* 1988; **29**: 1666–1671.
5 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 10th edn. New York: Wiley, 2000: 2199.

20 General References

van Uyl CH. Technical and commercial aspects of the use of lactitol in foods as a reduced-calorie bulk sweetener. *Dev Sweeteners* 1987; **3**: 65–81.
van Velthuijsen JA. Food additives derived from lactose: lactitol and lactitol palmitate. *J Agric Food Chem* 1979; **27**: 680–686.

21 Author

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22 Date of Revision

16 October 2002.