

## 18 Comments

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).

Lactitol is used therapeutically in the treatment of hepatic encephalopathy and as a laxative;<sup>(9)</sup> see also Section 14.

Lactitol has been investigated for use as a binder, but its high water solubility and hygroscopicity was found to limit its practical use.<sup>(3)</sup>

A specification for lactitol is included in the *Food Chemicals Codex* (FCC).<sup>(10)</sup>

The EINECS numbers for lactitol are 209-566-6 (anhydrous) and 209-566-5 (monohydrate).

## 19 Specific References

- Allen LV. Featured excipient: capsule and tablet diluents. *Int J Pharm Compound* 2000; 4(4): 306–310324–325.
- Armstrong NA. Direct compression characteristics of lactitol. *Pharm Technol Eur* 1998; 10(2): 42–46.
- Bolhuis GK, et al. Polyols as filler-binders for disintegrating tablets prepared by direct compaction. *Drug Dev Ind Pharm* 2009; 35(6): 671–677.
- Muzikova J, Vaiglova J. A study of the properties of tablets from the mixture of directly compressible starch and directly compressible lactitol. *Ceska Slov Form* 2007; 5(6): 183–189.
- European Food Safety Authority. Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to a notification from EPA on lactitol pursuant to Article 6, paragraph 11 of Directive 2000/13/EC- for permanent exemption from labelling. *The EFSA Journal* 2007; 565: 1–6.

- Grenby TH, et al. Studies on the dental properties of lactitol compared with five other bulk sweeteners *in vitro*. *Caries Res* 1989; 23: 315–319.
- Grimble GK, et al. Assimilation of lactitol, an unabsorbed disaccharide in the normal human colon. *Gut* 1988; 29: 1666–1671.
- Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 12th edn. New York: Wiley, 2012; 2698.
- van Schalk BA. Lactitol versus lactulose in constipation. *Pharm Weekblad* 1991; 126: 1133–1137.
- Food Chemicals Codex*. [online] Bethesda, MD: United States Pharmacopeia. <http://publications.usp.org> (accessed 31 March 2017).

## 20 General References

- Armstrong NA. Tablet manufacture. In: Swarbrick J, Boylan JC, eds. *Encyclopedia of Pharmaceutical Technology*, 2nd edn, 3. New York: Marcel Dekker, 2002: 2713–2732.
- Bolhuis GK, Armstrong NA. Excipients for direct compression – an update. *Pharm Dev Technol* 2006; 11: 111–124.
- 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 Velthuisen JA. Food additives derived from lactose: lactitol and lactitol palmitate. *J Agric Food Chem* 1979; 27: 680–686.
- United State Pharmacopeia. Material safety data sheet: Lactitol, May 2012. <http://www.usp.org/pdf/EN/referenceStandards/msds/1356687.pdf> (accessed 5 May 2015).

## 21 Author

ME Quinn.

## 22 Date of Revision

4 May 2017.

# Lactose, Anhydrous

## 1 Nonproprietary Names

BP: Lactose

JP: Anhydrous Lactose

PhEur: Lactose

USP–NF: Anhydrous Lactose

## 2 Synonyms

*Anhydrous 60M; Anhydrous 120M; Anhydrous DT; Anhydrous DT High Velocity; Anhydrous Impalpable; DuraLac H; Lactopress Anhydrous; Lactopress Anhydrous 250; Lactopress Anhydrous Crystals; Lactopress Anhydrous Microfine; Lactopress Anhydrous Powder; Lactopress Anhydrous Fine Powder; lactosum anhydricum; lattsio; milk sugar; SuperTab 21AN; SuperTab 22AN; SuperTab 24AN; saccharum lactis.*

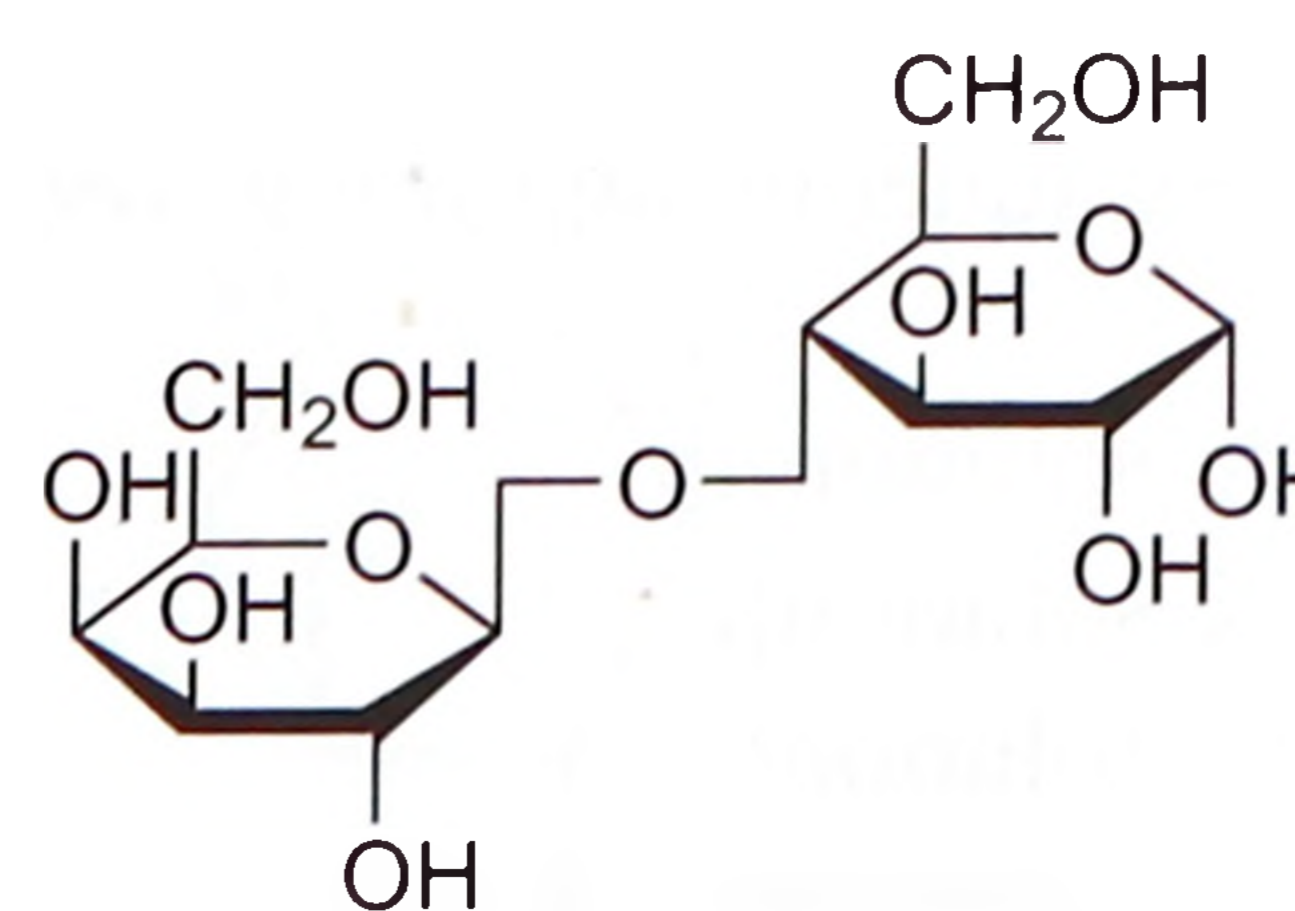
## 3 Chemical Name and CAS Registry Number

O-β-D-Galactopyranosyl-(1→4)-β-D-glucopyranose [63-42-3]

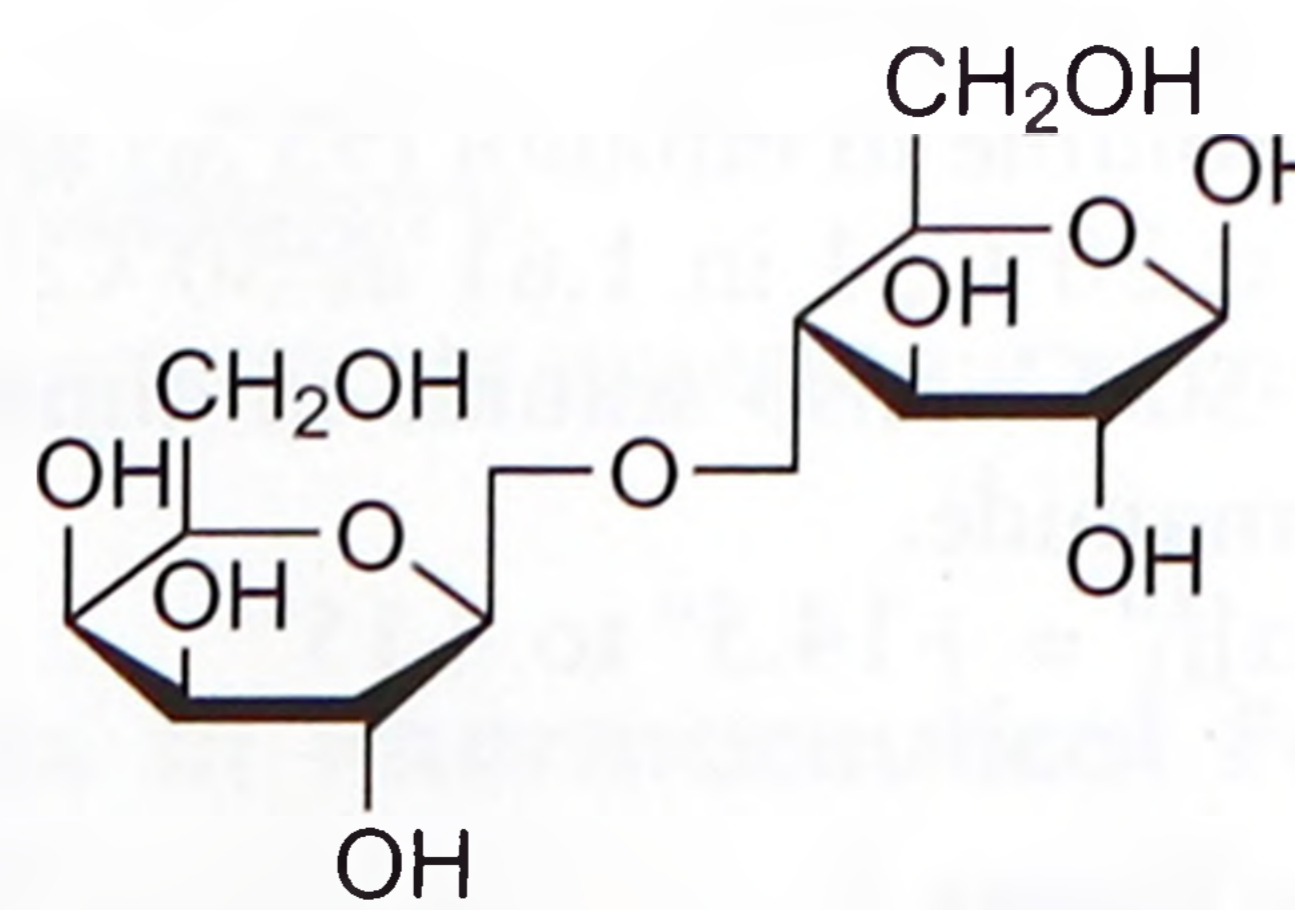
## 4 Empirical Formula and Molecular Weight

C<sub>12</sub>H<sub>22</sub>O<sub>11</sub> 342.30

## 5 Structural Formula



Anhydrous α-lactose



Anhydrous β-lactose

The PhEur 9.2 and USP 40–NF 35 S1 describe anhydrous lactose as O-β-D-galactopyranosyl-(1→4)-β-D-glucopyranose; or a mixture of O-β-D-galactopyranosyl-(1→4)-β-D-glucopyranose and O-β-D-galactopyranosyl-(1→4)-α-D-glucopyranose. The JP XVII describes anhydrous lactose as β-lactose or a mixture of β-lactose and α-lactose, and defines these as per the PhEur and USP–NF.