

**14 Safety**

Cellaburate has been used in oral pharmaceutical formulations, and is generally regarded as a safe material. It may cause slight skin irritation but no skin sensitization has been observed in guinea pigs.

LD<sub>50</sub> (guinea pig, skin): >1.0 g/kg (highest dose tested)<sup>(4)</sup>

LD<sub>50</sub> (rat, oral): >6.4 g/kg (highest dose tested)<sup>(4)</sup>

**15 Handling Precautions**

Observe normal precautions appropriate to the circumstances and quantity of the material handled. Precautions to prevent combustible dust concentrations in the air should be taken.

**16 Regulatory Status**

Included in the FDA Inactive Ingredients Database (oral extended-release tablets). Included in the Canadian Natural Health Products Ingredients Database.

**17 Related Substances**

Cellulose acetate; cellulose acetate phthalate.

**18 Comments**

Cellaburate has been used in the manufacture of hydrophobic contact lens materials.

**19 Specific References**

- 1 Yuan J *et al.* Tailoring permeability of coating films with cellulose esters polymers. IPCOM Patent 000181516D; 3 April 2009.
- 2 Shanbhag A, *et al.* Application of cellulose acetate butyrate-based membrane for osmotic drug delivery. *Cellulose* 2007; **14**(1): 65–71.
- 3 Kirsch JD, Xiao C. Extended release formulations resistant to alcohol dose dumping. International Patent WO 2014/151797 A1, 25 September 2014.
- 4 Eastman Chemical Company. Material safety data sheet: cellulose acetate butyrate, 2014.

**20 General References**

Eastman Chemical Company. Cellulose Esters for Pharmaceutical Drug Delivery. Kingsport, TN, USA, 2005. [http://www.eastman.com/Literature\\_Center/P/PCI105.pdf](http://www.eastman.com/Literature_Center/P/PCI105.pdf) (accessed 18 July 2015).

**21 Authors**

RC Moreton, C Rollins.

**22 Date of Revision**

4 May 2017.

## Cellulose Acetate

**1 Nonproprietary Names**

BP: Cellulose Acetate

PhEur: Cellulose Acetate

USP–NF: Cellulose Acetate

**2 Synonyms**

Acetic acid, cellulose ester; acetose; acetyl cellulose; cellulose diacetate; cellulose triacetate; cellulosi acetas; monoacetylcellulose

**3 Chemical Name and CAS Registry Number**

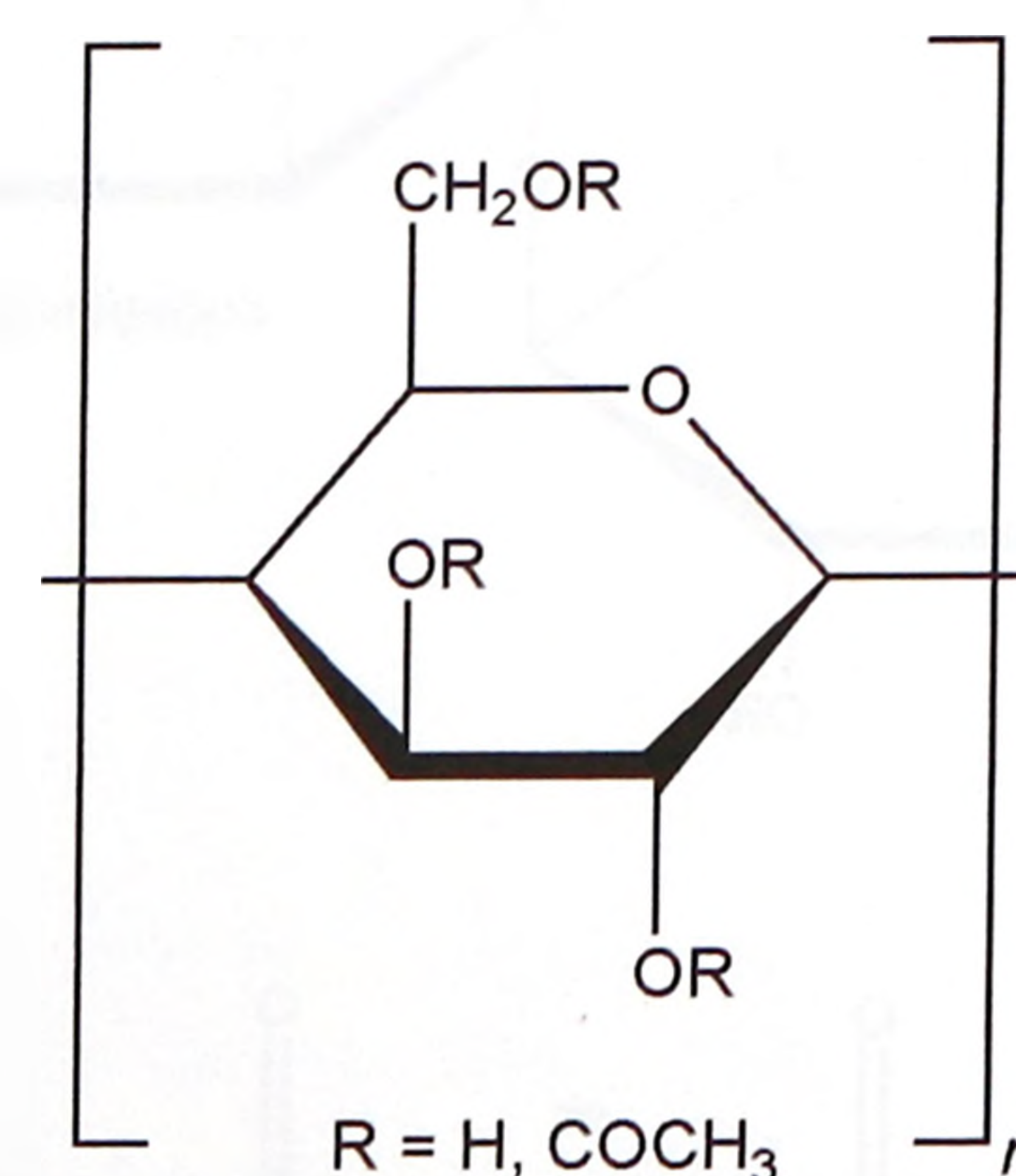
Cellulose acetate [9004-35-7]

Cellulose diacetate [9035-69-2]

Cellulose triacetate [9012-09-3]

**4 Empirical Formula and Molecular Weight**

Cellulose acetate is cellulose in which a portion or all of the hydroxyl groups are acetylated. Cellulose acetate is available in a wide range of acetyl levels and chain lengths and thus molecular weights and viscosities. It contains not less than 29.0% and not more than 44.8% by weight of acetyl groups, calculated on the dried basis; *see* Table I.

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

Coating agent; modified-release agent; tablet and capsule diluent; transdermal delivery component.

**7 Applications in Pharmaceutical Formulation or Technology**

Cellulose acetate is widely used in pharmaceutical formulations both in sustained-release applications and for taste masking.

Cellulose acetate is used as a semipermeable coating on tablets, especially on osmotic pump-type tablets and implants. This allows for controlled, extended release of actives.<sup>(1–5)</sup> Cellulose acetate films, in conjunction with other materials, also offer sustained