Polydextrose

1 Nonproprietary Names

None adopted.

2 Synonyms

E1200; *Litesse*; polydextrose A; polydextrose K.

3 Chemical Name and CAS Registry Number

Polydextrose [68424-04-4]

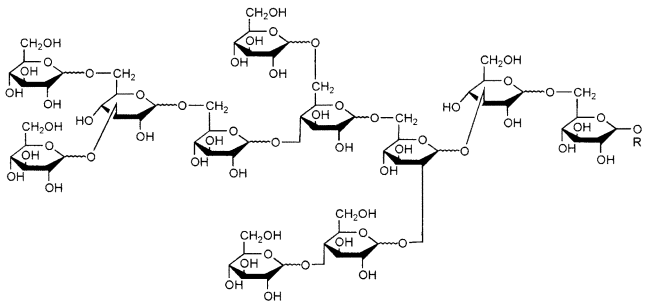
4 Empirical Formula

$(C_6H_{12}O_6)_x$

Molecular Weight

1200–2000 (average)

5 Structural Formula



See Section 18.

6 Functional Category

Base for medicated confectionery; coating agent; granulation aid; tablet binder; viscosity-increasing agent.

7 Applications in Pharmaceutical Formulation or Technology

Polydextrose is used in pharmaceutical formulations and food products. In food products it is used as a bulking agent; it also has texturizing and humectant properties.

Although polydextrose can be used in a wide range of pharmaceutical formulations, its primary use is in solid-dosage forms.

In tableting, polydextrose solutions are used as binders in wet-granulation processes. Polydextrose is also used in the manufacture of directly compressible tableting excipients. Polydextrose solutions may also be used, in conjunction with other materials, as a film and tablet coating agent.

Polydextrose acts as a bulking agent in the formulation of 'sugar-free' confectionary-type dosage forms. In conjunction with isomalt, lactitol, or maltitol, polydextrose can be used in the manufacture of 'sugar-free' hard-boiled candies and acacia lozenges or pastilles.

The combination of high water solubility and high viscosity of polydextrose facilitates the processing of sugar-free candies of excellent quality. Polydextrose is amorphous and does not crystallize at low temperatures or high concentrations, so it can be used to control the crystallization of polyols and sugars and therefore the structure and texture of the final product.

8 Description

Polydextrose occurs as an odorless, off white to light tan powder with a bland, slightly tart taste.

9 Pharmacopeial Specifications

See Section 18.

10 Typical Properties

Acidity/alkalinity: pH = 2.5 minimum (10% w/v aqueous solution)
Density (bulk): 0.625 g/cm^3
Density (tapped): 0.694 g/cm^3
Heat of solution: 8 kcal/g
Melting point: polydextrose is an amorphous polymer that does not have a melting range. However, it can undergo a viscosity transition at a temperature as low as 150–160°C.
Moisture content: at relative humidities above approximately 60%, polydextrose absorbs significant amounts of moisture; *see* Section 11. *See also* Figure 1.
Refractive index: n_D^{20} = 1.3477 (10% w/v aqueous solution)
Solubility: completely miscible in water. Sparingly soluble to insoluble in most organic solvents. Polydextrose has a higher water solubility than most carbohydrates and polyols, allowing the preparation of 80% w/v solutions at 20°C. Polydextrose is soluble in ethanol and only partially soluble in glycerin and propylene glycol.
Viscosity (dynamic): polydextrose solutions behave as Newtonian fluids. Polydextrose has a higher viscosity than sucrose or sorbitol at equivalent temperatures. This characteristic enables polydextrose to provide the desirable mouthfeel and textural qualities that are important when formulating syrups and viscous solutions. *See* Figure 2.

11 Stability and Storage Conditions

Polydextrose is hygroscopic and absorbs significant amounts of moisture at relative humidities greater than 60%. Under dry storage conditions it has good stability.

The bulk material should be stored in a cool, dry place in well-closed containers.

12 Incompatibilities

Incompatible with oxidizing agents, strong acids, and alkalis, forming a brown coloration and depolymerizing.

13 Method of Manufacture

Dextrose and sorbitol undergo a catalytic condensation reaction with an acid. Further purification may be performed to

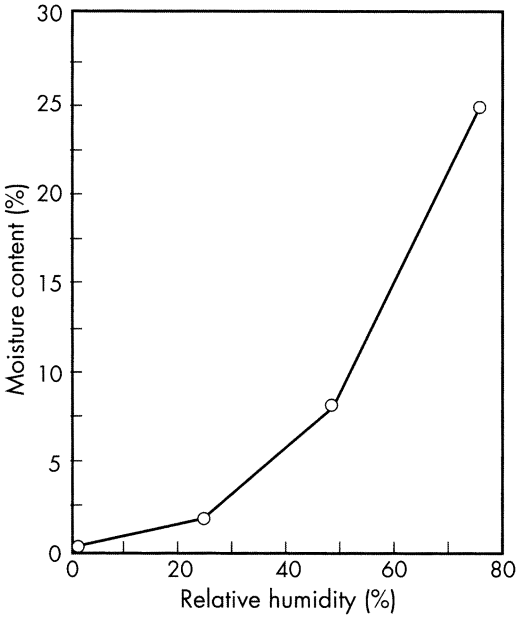


Figure 1: Moisture content of polydextrose at 20°C.

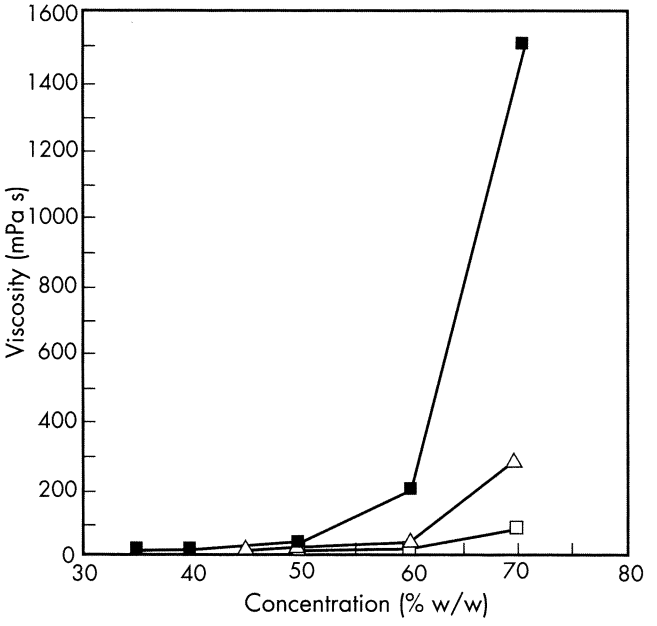


Figure 2: Viscosity of polydextrose solutions at 25°C at various concentrations.
△: Sucrose
■: Polydextrose
□: Sorbitol

remove acidity and flavor notes generated during the condensation.

14 Safety

Polydextrose is used in oral pharmaceutical applications, food products, and confectionery and is generally regarded as a relatively nontoxic and nonirritant material.

Polydextrose has been evaluated by the FAO/WHO Joint Expert Committee on Food Additives (JECFA), which has allocated an acceptable daily intake of 'not specified'. *See also* Section 18.

LD_{50} (mouse, oral): >30 g/kg
LD_{50} (rat, oral): >15 g/kg

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Polydextrose may be irritant to the eyes. Eye protection and gloves are recommended. Conventional dust-control practices should be employed.

16 Regulatory Status

GRAS listed. Accepted as a food additive in Europe.

17 Related Substances

Dextrose.

18 Comments

Polydextrose is a randomly bonded polymer prepared by the condensation of a melt that consists of approximately 90% w/w D-glucose, 10% w/w sorbitol, and 1% w/w citric acid or 0.1% w/w phosphoric acid.

The 1,6 glycosidic linkage predominates in the polymer, but other possible bonds are present. The product contains small quantities of free glucose, sorbitol, and D-anhydroglucoses (levoglucosan), with traces of citric or phosphoric acid.

Polydextrose may be partially reduced by transition-metal catalytic hydrogenation in aqueous solution. It may be neutralized with any food-grade base and/or decolorized and deionized for further purification.

Although not currently included in any pharmacopeias, a specification for polydextrose is contained in the Food Chemicals Codex (FCC IV). *See* Table I.

Table I: Food Chemicals Codex specifications for polydextrose.[1]

Test	FCC 1996 (Suppl 2)
Identification	+
Heavy metals	≤5 ppm
5-Hydroxymethylfurfural	≤0.1%
Lead	≤0.5 ppm
Molecular weight limit	+
Monomers	
1,6-Anhydro-D-glucose	≤4.0%
Glucose and sorbitol	≤6.0%
pH of a 10% solution	
Untreated	2.5–7.0
Neutralized	5.0–6.0
Residue on ignition	
Untreated	≤0.3%
Neutralized	≤2.0%
Water	≤4.0%
Assay	≥90.0%

Polydextrose is partially fermented by intestinal microorganisms to produce volatile fatty acids. The volatile fatty acids are absorbed in the large intestine. Because of the inefficient way the human body derives energy from volatile fatty acids, polydextrose contributes only one-quarter of the energy of the equivalent weight of sugar, i.e, ≈4 kJ/g (1 kcal/g).[2–4]

When consumed, polydextrose has a negligible effect on blood glucose levels. Polydextrose is metabolized independently of insulin and contributes only one quarter of the energy of normal carbohydrate.

A daily consumption of about 50 g of polydextrose, even if consumed as a single dose, is unlikely to cause gastrointestinal effects. The laxative effects of sugar replacers varies between individuals and depends on other factors such as daily diet and mode and frequency of ingestion. The mean laxative dose for polydextrose is 90 g/day.

19 Specific References

1 Committee on Food Chemicals Codex. *Food Chemicals Codex*, 4th edn. Washington, DC: National Academy Press, 1996: 297–300.

2 Figdor SK, Rennhard HH. Caloric utilization and disposition of [^{14}C]polydextrose in the rat. *J Agric Food Chem* 1981; **29**: 1181–1189.

3 Juhr N, Franke J. A method for estimating the available energy of incompletely digested carbohydrates in rats. *J Nutr* 1992; **122**: 1425–1433.

4 Achour L, Flourie B, Briet F, *et al*. Gastrointestinal effects and energy value of polydextrose in healthy non-obese men. *Am J Clin Nutr* 1994; **59**: 1362–1368.

20 General References

Allingham RP. *Chemistry of Foods and Beverages*: *Recent Developments*. New York: Academic Press, 1982: 293–303.

Slade L, Levine H. Glass transitions and water–food interaction. *Advances in Food and Nutrition Research*. San Diego: Academic Press, 1994.

21 Author

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22 Date of Revision

14 October 2002.