17 Related Substances

Dextrates; dextrin; dextrose; fructose; glucose liquid; polydextrose; sucrose.

18 Comments

Dextrose anhydrous is one of the materials that have been selected for harmonization by the Pharmacopeial Discussion Group. For further information see the General Chapter 5.8 in PhEur, along with the 'State of Work' document on the PhEur EDQM website, and also the General Information Chapter G10 in the JP.

The way in which the strengths of dextrose solutions are expressed varies from country to country. Approximately 1.1 g of dextrose monohydrate is equivalent to 1 g of anhydrous dextrose.

The BP 2017 directs that when Glucose Intravenous Infusion is required as a diluent for official injections or intravenous infusions, Glucose Intravenous Infusion 5% should be used.

A specification for dextrose anhydrous is contained in the Food Chemicals Codex (FCC).[12] The EINECS number for dextrose anhydrous is 200-075-1. The PubChem Compound ID (CID) for dextrose anhydrous include 5793 and 79025.

19 Specific References

1 Armstrong NA *et al.* The compressional properties of dextrose monohydrate and anhydrous dextrose of varying water contents. In: Rubinstein MH, ed. *Pharmaceutical Technology: Tableting Technology.* 1. Chichester: Ellis Horwood, 1987: 127–138.

2 Roquette. Product Monograph: Dextrose anhydrous. http://uc-pharma-en.roquette.boreades.argosit.net/dextrose-anhydrous-monomer-natural-sugar-pharmacopoeia-parenteral/# (accessed 6 March 2015).

3 Armstrong NA, *et al.* The compressional properties of dextrose monohydrate and anhydrous dextrose of varying water contents. *Drug Dev Ind Pharm* 1986; 12(11-13): 1885–1901.

4 Lerk CF, *et al.* Effect of dehydration on the binding capacity of particular hydrates. *J Pharm Pharmacol* 1984; 36: 399.

5 Motad A. X-Ray crystallographic study of alpha-Glucose at 140k. *Acta Chem Scand* 1994; 48: 276–278.

6 Brown GM, Levy HA. Alpha-D-glucose: further refinement based on neutron-diffraction data. *Acta Cryst* 1979; B35: 656–659.

7 Dujardin N, *et al.* Solid state vitrification of crystalline α and β-D-glucose by mechanical milling. *Solid State Communications* 2008; 148(1–2): 78–82.

8 Sigma-Aldrich. Material safety data sheet: D-(+)-Glucose, June 2014.

9 Lee JW, *et al.* Investigation of the heating rate dependency associated with the loss of crystalline structure in sucrose, glucose, and fructose using thermal analysis approach (part I). *J Agric Food Chem* 2011; 59(2): 684.

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11 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials,* 12th edn. New York: Wiley, 2012: 2280.

12 *Food Chemicals Codex.* [online] Bethesda, MD: United States Pharmacopeia. http://publications.usp.org (accessed 31 March 2017).

20 General References

European Directorate for the Quality of Medicines and Healthcare (EDQM). European Pharmacopoeia – State Of Work Of International Harmonisation. Pharmeuropa September 2014. http://pharmeuropa.edqm.eu/home/menupage/English/Pharmacopoeial%20Harmonisation/PDG_State_of_Work_E.pdf (accessed 2 March 2015).

21 Author

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22 Date of Revision

4 May 2017.

Dibutyl Phthalate

1 Nonproprietary Names

BP: Dibutyl Phthalate

PhEur: Dibutyl Phthalate

USP–NF: Dibutyl Phthalate

2 Synonyms

Araldite 502; benzenedicarboxylic acid, dibutyl ester; benzene-*o*-dicarboxylic acid di-*n*-butyl ester; butyl phthalate; *Celluflex DBP*; DBP; dibutyl 1,2-benzenedicarboxylate; dibutyl benzene 1,2-dicarboxylate; dibutyl ester of 1,2-benzenedicarboxylic acid; dibutylis phthalas; dibutyl-*o*-phthalate; di-*n*-butyl phthalate; *Eastman DBP*; *Elaol*; *Ergoplast FDB*; *Genoplast B*; *Hatcol DBP*; *Hexaplast M/B*; *Kodaflex DBP*; *Monocizer DBP*; *Palatinol C*; phthalic acid dibutyl ester; *Polycizer DBP*; *PX 104*; *RC Plasticizer DBP*; *Staflex DBP*; *Unimoll DB*; *Vestimol C*; *Witcizer 300*.

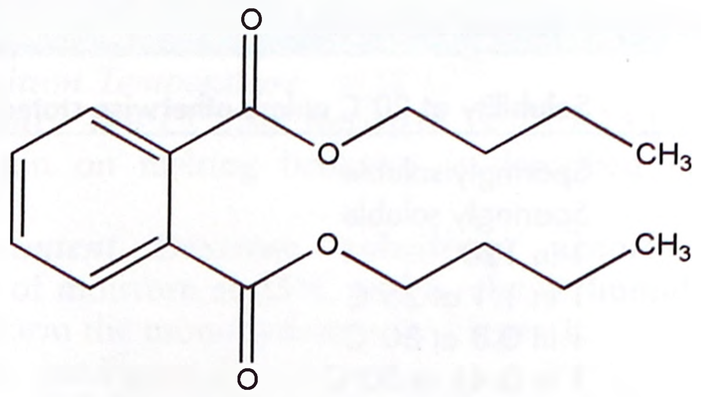
3 Chemical Name and CAS Registry Number

Dibutyl benzene-1,2-dicarboxylate [84-74-2]

4 Empirical Formula and Molecular Weight

$C_{16}H_{22}O_4$ 278.34

5 Structural Formula



6 Functional Category

Plasticizing agent; solvent.

7 Applications in Pharmaceutical Formulation or Technology

Dibutyl phthalate is used in pharmaceutical formulations as a plasticizing agent in film-coatings. It has been evaluated as a pore-forming agent in novel delivery systems,[3,4] and as a plasticizer in ocular inserts[5] and transdermal delivery systems.[6,7] It is also used