Dibutyl Phthalate

1 Nonproprietary Names

BP: Dibutyl phthalate PhEur: Dibutylis phthalas

2 Synonyms

Araldite 502; benzenedicarboxylic acid; 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; dibutyl-o-phthalate; di-n-butyl phthalate; Elaol; Ergoplast FDB; Genoplast B; Hatcol DBP; Hexaplast M/B; Kodaflex DBP; Monocizer DBP; Palanitol 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

1,2-Benzenedicarboxylic acid dibutyl ester [84-74-2]

4 Empirical Formula Molecular Weight $C_{16}H_{22}O_4$ 278.34

5 Structural Formula

6 Functional Category

Film-former; plasticizer; solvent.

7 Applications in Pharmaceutical Formulation or Technology

Dibutyl phthalate is used in pharmaceutical formulations as a plasticizer in film-coatings. It is also used extensively as a solvent particularly in cosmetic formulations such as antiperspirants, hair shampoos and hair sprays. In addition to a number of industrial applications, dibutyl phthalate is used as an insect repellent, although it is not as effective as dimethyl phthalate.

8 Description

Dibutyl phthalate occurs as an odorless, oily, colorless, or very slightly yellow-colored, viscous liquid.

9 Pharmacopeial Specifications

See Table I.

Table 1: Pharmacopeial specifications for dibutyl phthalate.

Test	PhEur 2002	
Identification	+	
Appearance	+	
Relative density	1.043-1.048	
Refractive index	1.490-1.495	
Acidity	+	
Related substances	+	
Water	≤0.2%	
Sulfated ash	≤0.1%	
Assay	99.0–101.0%	

10 Typical Properties

Boiling point: 340 °C Density: see Table II.

Flash point: 171 °C closed cup.

Melting point: $-35\,^{\circ}\text{C}$

Partition coefficient: Octanol : water = 4.50 Refractive index: $n_{\rm D}^{20}$ = 1.491–1.495

Solubility: very soluble in acetone, benzene, ethanol (95%),

and ether; soluble 1 in 2500 of water at 20 °C.

Viscosity (dynamic): see Table II.

Table II: Density and dynamic viscosity of dibutyl phthalate at specified temperatures.

Temperature (°C)	Density (g/cm ³)	Dynamic viscosity (mPa s)
0	1.0627	59
10	1.0546	33
20	1.0465	20
30	1.0384	13
40	1.0303	9
50	1.0222	7

11 Stability and Storage Conditions

Dibutyl phthalate should be stored in a well-closed container in a cool, dry, location. Containers may be hazardous when empty since they can contain product residues such as vapors and liquids.

12 Incompatibilities

Dibutyl phthalate reacts violently with chlorine. It also reacts with oxidizing agents, acids, bases, and nitrates.

13 Method of Manufacture

Dibutyl phthalate is produced from *n*-butanol and phthalic anhydride in an ester formation reaction.

14 Safety

Dibutyl phthalate is generally regarded as a relatively nontoxic material, although it has occasionally been reported to cause hypersensitivity reactions. It is widely used in topical cosmetic and some oral pharmaceutical formulations.

LD₅₀ (mouse, IV): 0.72 g/kg⁽¹⁾ LD₅₀ (mouse, oral): 5.3 g/kg LD₅₀ (rat, oral): 8.0 g/kg LD₅₀ (rat, IP): 3.05 g/kg

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Contact with the skin and eyes should be avoided. Decomposition produces toxic fumes, carbon monoxide and carbon dioxide.

In the USA, the permitted 8-hour exposure limit for dibutyl phthalate is 5 mg/m³. In the UK, the long-term (8-hour TWA) exposure limit for dibutyl phthalate is 5 mg/m³. The short-term (15-minute) exposure limit is 10 mg/m³. (2)

16 Regulatory Status

Included in the FDA Inactive Ingredients Guide (oral tablets). Included in nonparenteral medicines licensed in the UK (oral capsules, tablets, granules; topical creams and solutions).

17 Related Substances

Diethyl phthalate; dimethyl phthalate; dioctyl phthalate.

Dioctyl phthalate

Empirical formula: C₂₄H₃₈O₄ Molecular Weight: 390.55 CAS number: [117-84-0]

Synonyms: 1,2-benzenedicarboxylic acid bis(2-ethylhexyl) ester; bis(2-ethylhexyl) phthalate; di(2-ethylhexyl)phthalate; DEHP; DOP; Octoil.

Description: clear, colorless, odorless, and anhydrous liquid.

Boiling point: 384 °C

Flash point: 206 °C (closed cup).

Melting point: -50 °C Refractive index: $n_D^{20} = 1.50$

Solubility: soluble in conventional organic solvents; practically

insoluble in water.

18 Comments

The EINECS number for dibutyl phthalate is 201-557-4.

19 Specific References

- 1 Lewis RJ, ed. Sax's Dangerous Properties of Industrial Materials, 10th edn. New York: Wiley, 2000, 1172.
- 2 Health and Safety Executive. EH40/2002: Occupational Exposure Limits 2002. Sudbury: Health and Safety Executive, 2002.

20 General References

Wilson AS. *Plasticisers – Principles and Practice*. London: Institute of Materials, 1995.

21 Author

SC Owen.

22 Date of Revision

10 June 2002.