16 Regulatory Status

Included in the FDA Inactive Ingredients Database (oral capsules and tablets). Included in nonparenteral medicines licensed in the UK (oral capsules; topical creams and solutions). Included in the Canadian Natural Health Products Ingredients Database.

17 Related Substances

Diethyl phthalate; dimethyl phthalate; dioctyl phthalate.

Dioctyl phthalate

Empirical formula $C_{24}H_{38}O_4$
Molecular weight 390.55
CAS number Dioctyl phthalate occurs commercially in two isomeric forms: di-*n*-octyl phthalate [117-84-0] and di(2-ethylhexyl) phthalate [117-81-7].
Synonyms 1,2-Benzenedicarboxylic acid bis(2-ethylhexyl) ester; bis(2-ethylhexyl) phthalate; di(2-ethyl-hexyl)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.
Comments The EINECS number for dioctyl phthalate is 204-214-7.

18 Comments

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.

A specification for dibutyl phthalate is included in the *Japanese Pharmaceutical Excipients* (JPE).[8]

The EINECS number for dibutyl phthalate is 201-557-4. The PubChem Compound ID (CID) for dibutyl phthalate is 3026.

19 Specific References

1 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 12th edn. New York: Wiley, 2012: 1421.
2 Health and Safety Executive. *EH40/2005: Workplace Exposure Limits*. Sudbury: HSE Books, 2011. http://www.hse.gov.uk/pubns/priced/eh40.pdf (accessed 20 September 2015).
3 Choudhury PK, *et al.* Osmotic delivery of flurbiprofen through controlled porosity asymmetric membrane capsule. *Drug Dev Ind Pharm* 2007; 33(10): 1135–1141.
4 He L, *et al.* A novel controlled porosity osmotic pump system for sodium ferulate. *Pharmazie* 2006; 61(12): 1022–1027.
5 Pawar PK, *et al.* Design and evaluation of moxifloxacin hydrochloride ocular inserts. *Acta Pharm* 2012; 62(1): 93–104.
6 Pichayakorn W, *et al.* Transdermal nicotine mixed natural rubber-hydroxypropylmethylcellulose film forming systems for smoking cessation: *in vitro* evaluations. *Pharm Dev Technol* 2014; Aug 271–10.
7 Agrawal SS, Pruthi JK. Development and evaluation of matrix type transdermal patch of ethinylestradiol and medroxyprogesterone acetate for anti-implantation activity in female Wistar rats. *Contraception* 2011; 84(5): 533–538.
8 Japan Pharmaceutical Excipients Council. *Japanese Pharmaceutical Excipients* 2004. Tokyo: Yakuji Nippo, 2004: 228–229.

20 General References

ScienceLab. Material safety data sheet: Dibutyl phthalate, May 2013.
Wilson AS. *Plasticisers – Principles and Practice*. London: Institute of Materials, 1995.

21 Author

RT Guest.

22 Date of Revision

4 May 2017.

Dibutyl Sebacate

1 Nonproprietary Names

USP–NF: Dibutyl Sebacate

2 Synonyms

Bis(*n*-butyl)sebacate; butyl sebacate; DBS; decanedioic acid, dibutyl ester; dibutyl decanedioate; dibutyl 1,8-octanedicarboxylate; *Kodaflex DBS*; *Morflex DBS*; *Proviplast 1944*; sebacic acid dibutyl ester; *Stelliesters DBS*.

3 Chemical Name and CAS Registry Number

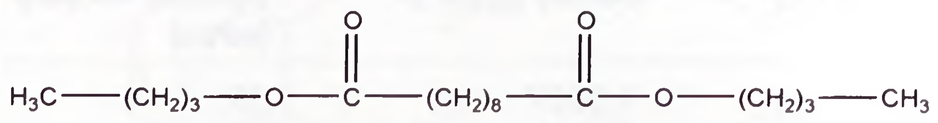
Decanedioic acid, di-*n*-butyl ester [109-43-3]

4 Empirical Formula and Molecular Weight

$C_{18}H_{34}O_4$ 314.47

The USP 40–NF 35 S1 describes dibutyl sebacate as consisting of the esters of *n*-butyl alcohol and saturated dibasic acids, principally sebacic acid.

5 Structural Formula



6 Functional Category

Plasticizing agent.

7 Applications in Pharmaceutical Formulation or Technology

Dibutyl sebacate is used in oral pharmaceutical formulations as a plasticizer for film coatings on tablets, beads, and granules, at concentrations of 10–30% by weight of polymer.[1–3] It is also used as a plasticizer in controlled-release tablets and microcapsule preparations.[4–7]

Dibutyl sebacate has been used in the preparation of controlled-release buccal and trandermal patches as a component of the adhesive.[8,9]