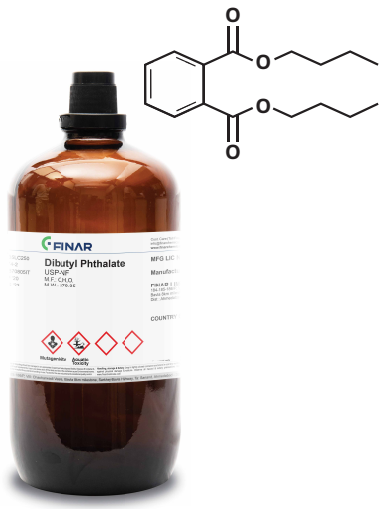
Technical Data Sheet

Dibutyl phthalate

IP, BP, Ph.Eur., USP-NF



Applications

Dibutyl phthalate is a commonly used excipient as a Plasticizer. The preferred route of application is through Solid oral and Topical dosage forms.

General Information

Pharmacopeia Status	:	IP, BP, Ph.Eur., USP-NF
CAS No.	:	84-74-2
EC No.	:	201-557-4
Appearance/Description	:	A clear, oily liquid, colourless or very slightly yellow
Molecular Formula	:	$C_{16}H_{22}O_4$
Molecular Mass	:	278.34 g/mol

Marketed Formulation

- Mesalamine 400 mg tablets
- Diltiazem 120 mg tablets & many more..

Quality and Regulatory Support

- GMP and ISO certification
- EXCiPACT certification
- Nitrosamine impurity risk assessment
- Elemental impurity risk assessment
- Residual solvent declaration
- Genotoxic impurity declaration
- Vendor questionnaire and site audit
- CMC documentation
- Regulatory queries

Key Product Attributes

- Manufacturing and packing under GMP environment
- Control of sub-visible particles

Pack Mode

- 500 ml, 2.5 Litre, 2.5 kg glass bottle
- 25 Litre HDPE container

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 vapours and liquids.

Safety and Handling Information

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. 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.

Pharmaceutical Specifications

Description/ Appearance	Clear, oily liquid, colourless or very slightly yellow (Not more intensely coloured than reference solution Y6. (BP, Ph.Eur, IP-2007, USP-NF)
Assay (anhydrous basis)	99.0%-101.0% (IP-2007 BP, Ph.Eur, USP-NF)
Solubility	Practically insoluble in water, miscible with ethanol (95%), ethanol (96%) and with ether (IP-2007, BP, Ph.Eur ,USP-NF)
Identification (By Relative density, 20°C)	1.043 - 1.048 (BP, Ph.Eur)
Identification (By Relative density, 25°C)	1.043 to 1.048 (IP-2007)
Identification (By TLC test)	The principal spot in the chromatogram obtained with the test solution should similar in position and size to the principal spot in the chromatogram obtained with the reference solution (BP, Ph.Eur, IP-2007)
Identification (By Refractive index, 20±0.5°C)	1.490 - 1.495 at 20°C (BP, Ph.Eur ,USP-NF, IP-2007)
Identification (By Chemical test)	To comply the test (IP-2007)
Identification (By IR)	IR spectra of the sample should be concomitant with IR spectra of the corresponding standard (BP, Ph.Eur)
Identification (By Chemical test)	The solution becomes yellow or brownish-yellow and shows a green fluorescence (BP, Ph.Eur)
Specific gravity, 20°C	1.043 - 1.048 (USP-NF)
Appearance of solution	The liquid under examination is clear and not more intensely coloured than reference solution YS6 (IP-2007, BP, Ph.Eur)
Appearance	Passes test (USP-NF)
Acidity	Not more than 0.50 mL of 0.1 M sodium hydroxide should require to change the colour of the indicator (BP, Ph.Eur, USP-NF, IP-2007)
Related substances	1.0% max (BP, Ph.Eur, USP-NF)
Sulphated ash / Residue on ignition	Not more than 0.1% (IP, BP, Ph.Eur, USP-NF)
Water	Not more than 0.2% (IP, BP, Ph.Eur, USP-NF)

Regulatory Information

Included in the FDA Inactive Ingredients Database (oral capsules, delayed action, enteric coated, and controlled release tablets) and in the non-parenteral medicines licensed in the UK (oral capsules, tablets, granules; topical creams and solutions).

Shipping Information

By Sea, Air and Road
Nature: Hazardous
UN Number: UN3082
Class: 9
Packaging group: III

See the Material Safety Data Sheet on www.finarchemicals.com

Note : The information contained herein is to our best knowledge true and accurate, but all recommendations or suggestions are made without guarantees since the conditions of use are beyond our control. Finar disclaims any liability incurred with the use of this data or suggestions.

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