

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identification:

Product Description: Dibutyl phthalate

Synonyms: DBP; n-Butyl phthalate, Phthalic acid dibutyl ester

CAS-No: 84-74-2 EC-No.: 201-557-4

Molecular Formula: C₁₆H₂₂O₄

1.2. Relevant identified uses of the substance or mixture and uses advised against:

Recommended Use: Used as pharma Excipient.

1.3. Details of the supplier of the safety data sheet:

• Company Finar Limited

184-186/P, Chacharwadi Vasna,

Sarkhej-Bavla Highway,

Ta.: Sanand, Dist.: Ahmedabad-382110, Gujarat, India.

Web: www.finarchemicals.com

• E-Mail Address safety.finar@actylis.com; info.finar@actylis.com

1.4. Emergency Telephone Number:

- For Emergency contact on: +91 - 2717 - 616 717



SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture:

Classification according to Regulation (EC) No 1272/2008

Reproductive toxicity (Category 1B), H360FD

Short-term (acute) aquatic hazard (Category 1), H400

Long-term (chronic) aquatic hazard (Category 2), H411

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2. Label Elements:

Labelling according Regulation (EC) No 1272/2008

Pictogram



Signal word: Danger

Hazard statement(s)

H360FD May damage fertility. May damage the unborn child.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statement(s)

P201 Obtain special instructions before use.

P273 Avoid release to the environment.

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Supplemental Hazard Statements

None

Restricted to professional users.

2.3. Other Hazards:

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS



Product Name	Dibutyl Phthalate

3.1. Substances: Dibutyl phthalate

3.2. Mixtures:

Component	CAS-No	EC-No.	Weight %
Dibutyl phthalate	84-74-2	201-557-4	<= 100 %

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures:

• General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

• If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration.

Consult a physician.

• If Contact with skin

Wash off with soap and plenty of water. Consult a physician.

• In case of eye contact

Flush eyes with water as a precaution.

• If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water.

Consult a physician.

4.2. Most important symptoms and effects, both acute and delayed:

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3. Indication of any immediate medical attention and special treatment needed:

No information Available

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media:

Suitable Extinguishing Media - Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2. Special hazards arising from the substance or mixture:

Carbon oxides

Combustible.



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5.3. Advice for firefighters:

Wear self-contained breathing apparatus for fire fighting if necessary.

5.4 Further Information:

No information Available

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures:

Use personal protective equipment. Avoid breathing vapours, mist or gas. Ensure adequate ventilation.

Evacuate personnel to safe areas.

For personal protection see section 8.

6.2. Environmental precautions:

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Discharge into the environment must be avoided.

6.3. Methods and material for containment and cleaning up:

Soak up with inert absorbent material and dispose of as hazardous waste.

Keep in suitable, closed containers for disposal.

6.4. Reference to other sections:

For disposal see Sections 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling:

Avoid exposure - obtain special instructions before use. Avoid inhalation of vapour or mist.

7.2. Conditions for safe storage, including any incompatibilities:

Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Store in cool place.

7.3. Specific end use(s):

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters:

Components with workplace control parameters

8.2. Exposure Controls:

Appropriate Engineering Controls:



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Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal Protective Equipment:

Eye & Face Protection-

Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Hand Protection –

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

Full contact:

Glove material: Nitrile Rubber

Glove thickness: 0.4 mm
Break through time: 480 min

Splash contact:

Glove material: Nature latex/chloroprene

Glove thickness: 0.6 mm

Break through time: 120 min

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

- Body Protection-

Impervious clothing, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

- Respiratory Protection-

Where risk assessment shows air-purifying respirators are appropriate use a fullface respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

- Environmental Exposure Controls-

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.



Discharge into the environment must be avoided.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties:

• **Appearance:** Clear

• Color: Colorless

Physical State: Liquid

• Odor: ester like

• Odor Threshold: No data available

• **pH:** Neutral at 10 g/l 20 °C

• Melting Point: -35 °C

• Critical Temperature: No data available

• Vapor Pressure: ca. 97.000 hPa at ca.25 °C

• Vapor Density: 9.58

• **Relative Density:** 1.043 g/cm3 at 25 °C

• Specific Gravity / Density: 1.043 g/cm³

• Auto-Ignition Temperature: 390 °C

• Decomposition Temperature: No data available

• Volatility: No data available

• Bulk Density: No data available

• Viscosity: 18.8 mm2/s at 20 °C

• Viscosity, Kinematic: No data available

• Water/Oil Dist. Co eff.: No data available

• Partition Co-efficient: n-octanol/Water: No data available

• **Ionicity (in Water):** No data available

Lower Explosion Limit: 0.5% @ 235°C

• Upper Explosion Limit: 2.5%

• **Boiling Point/Range:** 340 °C

• Flash Point: 157 °C

• Water Solubility: No information available

• Molecular Weight: 278.34

9.2. Other information:



Molecular Formula: C₁₆H₂₂O₄

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

No data available

10.2. Chemical stability:

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions:

No data available

10.4. Conditions to avoid:

No data available

10.5. Incompatible materials:

Strong oxidizing agents, Nitrates, Bases, acids, Chlorine

10.6. Hazardous decomposition products:

Hazardous decomposition products formed under fire conditions. - Carbon oxides

Other decomposition products - No data available

In the event of fire: see section 5

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:

Acute Oral toxicity

LD50 Oral - Rat - male and female - 6.279 mg/kg

(OECD Test Guideline 401)

LC50 Inhalation - Rat - male and female - 4 h - >= 15,68 mg/l

Remarks: (ECHA)

LD50 Dermal - Rabbit - > 21.000 mg/kg

Remarks: (RTECS)

Acute inhalation toxicity

No data available

Acute dermal toxicity

No data available

Skin irritation

Skin - Rabbit

Result: No skin irritation - 4 h



(OECD Test Guideline 404)

Eye irritation

Eyes - Rabbit

Result: No eye irritation - 72 h

(OECD Test Guideline 405)

Respiratory or skin sensitisation

Maximisation Test - Guinea pig

Result: negative

(OECD Test Guideline 406)

Germ cell mutagenicity

Ames test

S. typhimurium

Result: negative

(ECHA)

Mouse

Result: negative

(ECHA)

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

May damage the unborn child.

May damage fertility.

Teratogenicity

No data available

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

11.2 Further Information:

Repeated dose toxicity - Rat - male and female - Oral - 90 d - No observed adverse effect level - 152 mg/kg - Lowest observed adverse effect level - 752 mg/kg



Subchronic toxicity RTECS: TI0875000

Nausea, Dizziness, Headache

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity:

Toxicity to fish

Static test LC50 - Lepomis macrochirus (Bluegill sunfish) - ca. 0.48 mg/l - 96 h (OECD Test Guideline 203)

Toxicity to daphnia and other aquatic invertebrates

Static test EC50 - Daphnia magna (Water flea) - ca. 2.99 mg/l - 48 h (US-EPA)

Toxicity to algae

Static test EC50 - Pseudokirchneriella subcapitata (green algae) -0.75 mg/l - 10 d (US-EPA)

Static test NOEC - Pseudokirchneriella subcapitata (green algae) -0.39 mg/l - 10 d (US-EPA)

Toxicity to bacteria

EC50 - Tetrahymena pyriformis – 2.2 mg/l - 24 h

Remarks: (ECHA)

12.2 Persistence and degradability:

Biodegradability Result: 81 % - Readily biodegradable.

(Regulation (EC) No. 440/2008, Annex, C.4-C)

12.3 Bioaccumulate potential:

Bioaccumulation Pimephales promelas (fathead minnow) - 11 d

- 0,0348 mg/l (Dibutyl phthalate)

Bioconcentration factor (BCF): 2.165

Remarks: Does not bioaccumulate.

12.4 Mobility in soil:

No data available

12.5 Results of PBT and vPvB assessment:

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at



Product Name	Dibutyl Phthalate

levels of 0.1% or higher.

12.6 Other adverse effects:

Very toxic to aquatic life.

Discharge into the environment must be avoided.

SECTION 13: Disposal considerations

13.1 Waste treatment methods:

Product

Offer surplus and non-recyclable solutions to a licensed disposal company. Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself.

Contaminated packaging

Dispose of as unused product.

SECTION 14: Transport information

	Land transport (ADR/RID)	Air transport (IATA)	Sea transport (IMDG)	
14.1 UN number	UN 3082			
14.2 Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Dibutyl phthalate).			
14.3 Class	9			
14.4 Packing group	III			
14.5 Environmentally hazardous	Yes			
14.6 Special precautions for user	-			
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code				
Not Relevant				

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

Authorisations and/or restrictions on use

REACH - Candidate List of Substances of Very : Dibutyl phthalate



High Concern for Authorisation (Article 59).

This product contains a substance listed on Annex XIV of the REACH Regulation (EC) Nr. 1907/2006.

REACH - Restrictions on the manufacture,

: Dibutyl phthalate

placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)

15.2 Chemical safety assessment:

For this product a chemical safety assessment was not carried out.

SECTION 16: Other information

Full text of H-Statements referred to under sections 2 and 3.

H360FD May damage fertility. May damage the unborn child.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

H411 Toxic to aquatic life with long lasting effects.

Relevant changes since previous version

2. Hazards identification

Relevant changes since previous version

7. Handling and storage

References: Not available

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