

1. Product and company identification

Product identifier

Trade name: 617P37 - Hardener Powder

Relevant identified uses of the substance or mixture and uses advised against

General use: Curing agent for reactive resins for orthopedic procedures.
For commercial user only

Details of the supplier of the safety data sheet

Company name: Otto Bock Health Care
 Street/POB-No.: 3820 W. Great Lakes Drive
 Postal Code, city: Salt Lake City, UT 84120
 USA
 WWW: www.ottobockus.com
 Telephone: +1 (801) 956-2400
 Telefax: +1 (801) 956-2401
 Dept. responsible for information:
 Quality Department,
 Telephone: +1 (801) 954-2304 (7 AM – 3 PM, Mountain Time),
 Email: USRegulatory@ottobock.com

Additional information: Corporate headquarters:
 Ottobock SE & Co. KGaA
 Max-Näder-Straße 15
 Duderstadt
 Germany

Emergency phone number

CHEMTREC, Telephone: +1 (800) 424-9300
Transport:
CONSULTANK Lutz Harder GmbH (Contract QUALI003)
Telephone: +49 (0)178-4337434 (from USA: 01149 178 4337434)

2. Hazards identification

Emergency overview

Appearance: Physical state at 68 °F and 101.3 kPa: solid
 Form: Powder
 Color: white
 Odor: weak
 Classification: Organic Peroxide - Category D; Eye Irritation - Category 2A; Sensitization - skin - Category 1; Reproductive toxicant - Category 1B; Aquatic toxicity - acute - Category 1; Aquatic toxicity - chronic - Category 1;

Hazard symbols:



Signal word: **Danger**

617P37 - Hardener Powder

Material number 617P37

Hazard statements: Heating may cause a fire.
 May cause an allergic skin reaction.
 Causes serious eye irritation.
 May damage the unborn child.
 Very toxic to aquatic life with long lasting effects.

Precautionary statements: Obtain special instructions before use.
 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
 Keep only in original container.
 Avoid release to the environment.
 Wear protective gloves/protective clothing/eye protection.
 IF exposed or concerned: Get medical advice/attention.
 In case of fire: Use Foam, dry chemical powder or carbon dioxide to extinguish.
 Collect spillage.
 Store at temperatures not exceeding 25 °C/77 °F.

Regulatory status

This material is considered hazardous by the U.S. OSHA Hazard Communication Standard (29 CFR 1910.1200) and SIMDUT in Canada.

Hazards not otherwise classified

People who suffer from skin sensitization problems, asthma, allergies, chronic or recurring respiratory illnesses should not be deployed in any process using this preparation.

Dust explosive

see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: Powder-mixture.

Relevant ingredients:

CAS No.	Designation	Content	Classification
CAS 94-36-0	Dibenzoyl peroxide	30 - 60 %	Organic Peroxide - Category B. Eye Irritation - Category 2A. Sensitization - skin - Category 1. Aquatic toxicity - acute - Category 1. Aquatic toxicity - chronic - Category 1.
CAS 84-61-7	Dicyclohexyl phthalate	30 - 60 %	Sensitization - skin - Category 1. Reproductive toxicant - Category 1B. Aquatic toxicity - chronic - Category 3.

4. First aid measures

General information: In case of accident or if you feel unwell, seek medical advice immediately.
 IF exposed or concerned: Get medical advice/attention.
 First aider: Pay attention to self-protection!

In case of inhalation: Move victim to fresh air; if necessary, provide artificial respiration or oxygen. Immediately get medical attention.

617P37 - Hardener Powder

Material number 617P37

Page: 3 of 10

- Following skin contact: Take off immediately all contaminated clothing and wash it before reuse. Wash with generous amount of water and soap. Immediately get medical attention.
- After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Remove contact lenses, if present and easy to do. Continue rinsing. Subsequently consult an ophthalmologist.
- After swallowing: Immediately get medical attention. Do not induce vomiting without medical assistance. In case of vomiting, lay at least head on side. Never give anything by mouth to an unconscious person. Inhalation during vomiting: lung damages

Most important symptoms/effects, acute and delayed

May cause an allergic skin reaction. Causes serious eye irritation.
In case of inhalation/after contact with skin: Irritant effects are possible.

Information to physician

Treat symptomatically.
Call a POISON CENTER.
Inhalation during vomiting: lung damages. Due to risk of aspiration gastric lavage may only be applied under endotracheal intubation.
Symptoms may develop several hours following exposure; medical observation therefore necessary for at least 48 hours.

5. Fire fighting measures

- Flash point/flash point range: Not applicable
- Auto-ignition temperature: Danger of spontaneous combustion.
- Suitable extinguishing media: Foam, dry chemical powder, carbon dioxide
- Extinguishing media which must not be used for safety reasons: Full water jet

Specific hazards arising from the chemical

- Decomposition under heating. Heating may cause a fire.
In a case of fire, the product supports the burning process.
In case of fire may be liberated: Organic materials, carbon monoxide and carbon dioxide.
- Protective equipment and precautions for firefighters: Wear self-contained positive pressure breathing apparatus and full firefighting protective clothing.
- Additional information: In case of fire and/or explosion do not breathe fumes.
Prevent subsequent re-ignition with abundant quantities of water.
Cool endangered containers with water jetspray.
Do not allow fire water to penetrate into surface or ground water.

617P37 - Hardener Powder

Material number 617P37

Page: 4 of 10

6. Accidental release measures

- Personal precautions:** Avoid exposure. Eliminate all ignition sources if safe to do so.
Wear appropriate protective equipment. Take off immediately all contaminated clothing and wash it before reuse. Keep unprotected people away.
Avoid generation of dust. Do not breathe dust. Avoid contact with eyes and skin.
Provide adequate ventilation.
- Environmental precautions:** Do not allow to penetrate into soil, waterbodies or drains. If necessary notify appropriate authorities.
- Methods for clean-up:** Take up mechanically, placing in appropriate containers for disposal. Waste shall NOT be closed in tight.
Avoid generation of dust.

7. Handling and storage**Handling**

- Advices on safe handling:** Obtain special instructions before use. Avoid contact with skin, eyes, and clothing. Take off immediately all contaminated clothing and wash it before reuse.
Avoid generation of dust. Do not breathe dust. Provide adequate ventilation, and local exhaust as needed.
When using do not eat, drink or smoke. Wash hands before breaks and after work.
Separate storage of work clothes. Contaminated work clothing should not be allowed out of the workplace.
Avoid contact during pregnancy/while nursing.
Safety shower and eye wash station should be easily accessible to the work area.
- Precautions against fire and explosion:**
Keep away from sources of ignition - No smoking. Use only spark proof tools.
Use only explosion-proof equipment.
Avoid shock and friction. Protect from: warmth

Storage

- Requirements for storerooms and containers:**
Keep container dry. Keep container in a well-ventilated place.
Keep container tightly closed in a cool place.
Storage temperature: <77 °F. Protect from heat and direct sunlight.
Keep only in original container.
Storage according to local and national regulations.
- Hints on joint storage:** Keep away from amines, acids, basic agents, heavy metals (e.g. from accelerating agents and drying materials).
Avoid contact with iron and copper .
Keep away from food, drink and animal feedingstuffs.
- Further details:** Danger of spontaneous combustion.

8. Exposure controls / personal protection

Exposure guidelines

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
94-36-0	Dibenzoyl peroxide	USA: ACGIH: TWA	5 mg/m ³
		USA: NIOSH: TWA	5 mg/m ³
		USA: OSHA: TWA	5 mg/m ³

Engineering controls

Provide adequate ventilation.

Use only explosion-proof equipment. Use only spark proof tools.

See also information in chapter 7, section storage.

Personal protection equipment (PPE)

Eye/face protection Tightly sealed goggles according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2010.

Skin protection Wear suitable protective clothing.
 Protective gloves according to OSHA Standard - 29 CFR: 1910.138.
 Glove material: butyl caoutchouc (butyl rubber)
 Breakthrough time: >480 min
 Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Respiratory protection: Respiratory protection must be worn whenever the TLV (WEL) levels have been exceeded. Half mask with particle filter P2 according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2.

General hygiene considerations:

Obtain special instructions before use.
 Avoid contact with skin, eyes, and clothing. Avoid generation of dust. Do not breathe dust.
 When using do not eat, drink or smoke.
 Wash hands before breaks and after work.
 Take off immediately all contaminated clothing and wash it before reuse.
 Safety shower and eye wash station should be easily accessible to the work area.
 Avoid contact during pregnancy/while nursing.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:	Physical state at 68 °F and 101.3 kPa: solid Form: Powder Color: white
Odor:	weak
Odor threshold:	No data available
pH value:	not applicable
Melting point/freezing point:	> 104 °F
Initial boiling point and boiling range:	No data available
Flash point/flash point range:	Not applicable
Evaporation rate:	No data available
Flammability:	No data available

617P37 - Hardener Powder

Material number 617P37

Page: 6 of 10

Explosion limits:	No data available
Vapor pressure:	No data available
Vapor density:	No data available
Density:	at 68 °F: 1.23 g/cm ³
Water solubility:	at 68 °F: insoluble
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	Danger of spontaneous combustion.
Thermal decomposition:	SADT: 140 °F
Explosive properties:	Dust explosive
Bulk density:	at 68 °F: 620 - 650 kg/m ³
Additional information:	Contents of active oxygen: 1.9 - 3.8%

10. Stability and reactivity

Reactivity:	Heating may cause a fire. Decomposition under heating.
Chemical stability:	Stable under recommended storage conditions. (Refer to section 7) Hazardous, self-accelerating decomposition reaction is possible. Under certain conditions an explosion or fire may occur as a result of direct contact with incompatible substances or through thermal decomposition. Critical temperature: 131 °F.
Possibility of hazardous reactions	Danger of dust explosion!
Conditions to avoid:	Avoid shock and friction. Protect from heat and direct sunlight.
Incompatible materials:	Violent reactions may be expected with contact with acids, lyes, heavy metals and reducing agents. Avoid contact with rust. Do not mix with peroxide accelerants. Do not mix with reducing agents. Avoid contact with heavy metals and metal salts .
Hazardous decomposition products:	No hazardous decomposition products when regulations for storage and handling are observed.
Thermal decomposition:	SADT: 140 °F

11. Toxicological information

Toxicological tests

Toxicological effects:

- Acute toxicity (oral): Based on available data, the classification criteria are not met. ATEmix calculated: 2,000 mg/kg < ATE <= 5,000 mg/kg.
- Acute toxicity (dermal): Based on available data, the classification criteria are not met. ATEmix calculated: 2,000 mg/kg < ATE <= 5,000 mg/kg.
- Acute toxicity (inhalative): Based on available data, the classification criteria are not met. ATEmix calculated (Vapors):ATE >= 20 mg/L.
- Skin corrosion/irritation: Based on available data, the classification criteria are not met.
- Serious eye damage/irritation: Eye Irritation - Category 2A = Causes serious eye irritation.
- Sensitisation to the respiratory tract: Lack of data.
- Skin sensitisation: Sensitization - skin - Category 1 = May cause an allergic skin reaction.
- Germ cell mutagenicity/Genotoxicity: Based on available data, the classification criteria are not met. No mutagenity, after different in-vitro studies.
- Carcinogenicity: Lack of data.
- Reproductive toxicity: Reproductive toxicant - Category 1B = May damage the unborn child.
- Effects on or via lactation: Lack of data.
- Specific target organ toxicity (single exposure): Lack of data.
- Specific target organ toxicity (repeated exposure): Lack of data.
- Aspiration hazard: Based on available data, the classification criteria are not met.

Other information:

- Information about dibenzoyl peroxide:
 - Acute toxicity:
 - LD50 Rat, oral: >5,000 mg/kg bw
 - LC50 Rat, inhalative: > 24.3 mg/L/4h (OECD 403)
 - Information about Dicyclohexyl phthalate:
 - Acute toxicity:
 - LD50 Rat, oral: >2,000 mg/kg bw
 - LD50 Rat, dermal: > 2,000 mg/kg (OECD 402)
 - For carcinogenic effects:
 - Information about CAS No. 94-36-0
 - Carcinogen Status:
 - IARC Rating: Group 3
 - OSHA Carcinogen: not listed
 - NTP Rating: not listed

Symptoms

- In case of inhalation: Irritant effects are possible.
- After contact with skin: Dibenzoyl peroxide (78%): mild irritant.

12. Ecological information

Ecotoxicity

Aquatic toxicity: Very toxic to aquatic life with long lasting effects.

Information about Dibenzoyl peroxide:
 Algae toxicity: Pseudokirchneriella subcapitata (green algae) EC50: 0.06 mg/L /72h.
 Bacterial toxicity: activated sludge EC50: 35 mg/L. (OECD 209)
 Daphnia toxicity: EC50 Daphnia magna: 0.11 mg/L /48 h. (OECD 202)
 Daphnia toxicity: EC10 Daphnia magna: 0.001 mg/L /21d.
 Fish toxicity: Oncorhynchus mykiss LC50: 0.06 mg/L /96 h. (OECD 203)

Information about Dicyclohexyl phthalate:
 Algae toxicity: Pseudokirchneriella subcapitata (green algae) EC50: > 2 mg/L /72h.(OECD 201)
 Bacterial toxicity: activated sludge EC50:> 100 mg/L. (OECD 209)
 Daphnia toxicity: NOEC Daphnia magna: 0.18 mg/L /21d. (OECD 211)
 Fish toxicity: Oryzias latipes LC50: > 2 mg/L /96 h. (OECD 203)

Mobility in soil

No data available

Persistence and degradability

Further details: Product is biodegradable. The statement is derived from the properties of the single components.

Additional ecological information

Volatile organic compounds (VOC):
 0 % by weight

General information: Do not allow to penetrate into soil, waterbodies or drains.

13. Disposal considerations

Product

Recommendation: Incinerate as hazardous waste according to applicable local, state, and federal regulations.

Contaminated packaging

Recommendation: Dispose of waste according to applicable legislation.
 Attention: Empty containers will retain product residue and are to handle as though they are full.

617P37 - Hardener Powder

Material number 617P37

14. Transport information

USA: Department of Transportation (DOT)

Identification number: UN3106
 Proper shipping name: UN 3106, UN 3106, ORGANIC PEROXIDE TYPE D, SOLID (dibenzoyl peroxide)
 Hazard class or Division: 5.2
 Packing Group: II
 Labels: 5.2
 Symbols: G
 Packaging – Exceptions: 152
 Packaging – Non-bulk: 225
 Packaging – Bulk: None
 Quantity limitations – Passenger aircraft / rail: 5 kg
 Quantity limitations – Cargo only: 10 kg
 Vessel stowage – Location: D
 Vessel stowage – Other: 12, 25, 52, 53



Sea transport (IMDG)

UN number: UN 3106
 Proper shipping name: UN 3106, ORGANIC PEROXIDE TYPE D, SOLID (dibenzoyl peroxide)
 Class or division, Subsidiary risk: Class 5.2, Subrisk -
 Packing Group: -
 EmS: F-J, S-R
 Special provisions: 122, 274
 Limited quantities: 500 g
 Excepted quantities: E0
 Contaminated packaging - Instructions: P520
 Contaminated packaging - Provisions: -
 IBC - Instructions: -
 IBC - Provisions: -
 Tank instructions - IMO: -
 Tank instructions - UN: -
 Tank instructions - Provisions: -
 Stowage and handling: Category D. SW1
 Segregation: SG35 SG36
 Properties and observations: Decomposes at elevated temperatures or in a fire. Burns vigorously. Insoluble in water except for 3-chloroperoxybenzoic acid. Contact with the eyes and skin should be avoided. May evolve irritant or toxic fumes.
 Marine pollutant: yes
 Segregation group: none

Air transport (IATA)

UN/ID number: UN 3106
 Proper shipping name: UN 3106, ORGANIC PEROXIDE TYPE D, SOLID (dibenzoyl peroxide)
 Class or division, Subsidiary risk: Class 5.2
 Hazard label: Organic peroxide
 Excepted Quantity Code: E0
 Passenger and Cargo Aircraft: Ltd.Qty.: Forbidden
 Passenger and Cargo Aircraft: Pack.Instr. 570 - Max. Net Qty/Pkg. 5 kg
 Cargo Aircraft only: Pack.Instr. 570 - Max. Net Qty/Pkg. 10 kg
 Special provisions: A20 A802
 Emergency Response Guide-Code (ERG): 5L

Further information

Protect from heat and direct sunlight.

15. Regulatory information

National regulations - U.S. Federal Regulations

Dibenzoyl peroxide: TSCA Inventory: listed
 TSCA HPVC: not listed
 Carcinogen Status:
 IARC Rating: Group 3
 OSHA Carcinogen: not listed
 NTP Rating: not listed
 Other Environmental Laws:
 SARA Title III Section 313, Toxic Release: Conc. 1.0% / Threshold Standard
 NIOSH Recommendations:
 Occupational Health Guideline: 0052
 OSHA Process Safety Management: Threshold 7500 lbs.

National regulations - Great Britain

Hazchem-Code: 1WE

16. Other information

Text for labeling: Contains 30 - 60 % Dibenzoyl peroxide, 30 - 60 % Dicyclohexyl phthalate. Safety data sheet available on request.

Hazard rating systems:



NFPA Hazard Rating:
 Health: 2 (Moderate)
 Fire: 2 (Moderate)
 Reactivity: 3 (Serious)
 Precautions: OX (Material possesses oxidizing properties)

HMIS Version III Rating:
 Health: 2 (Moderate) - Chronic effects
 Flammability: 2 (Moderate)
 Physical Hazard: 3 (Serious)
 Personal Protection: X = Consult your supervisor

HEALTH	*	2
FLAMMABILITY		2
PHYSICAL HAZARD		3
		X

Literature: The SADT (self-accelerating decomposition temperature) is an experimentally determined temperature at which the product, in its conventional packaging, will decompose in a self-accelerating reaction.

Reason of change: Changes in section 1.3: Corporate headquarters
 Date of first version: 10/19/1994

Department issuing data sheet

Contact person: see section 1: Dept. responsible for information

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.