

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

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: Form: Powder, free flowing

Color: white

Odor: weak

Classification: Organic Peroxide - Category D; Eye Irritation - Category 2A; Sensitization - skin - Category 1; Reproductive toxicant - Category 2; Aquatic toxicity - chronic - Category 1;

Hazard symbols:



Signal word:

Danger

Hazard statements:

Heating may cause a fire.
May cause an allergic skin reaction.
Causes serious eye irritation.
Suspected of damaging fertility.
Very toxic to aquatic life with long lasting effects.

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Precautionary statements:

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
 Keep away from clothing as well as other incompatible materials.
 Avoid release to the environment.
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 Protect from sunlight. Store in a well-ventilated place.

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.

Explosive when dry.
 see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: Powder contains water (2%) and Silicon dioxide (1,5%).

Hazardous ingredients:

CAS No.	Designation	Content	Classification
CAS 94-36-0	Dibenzoyl peroxide	40 - 55 %	Organic Peroxide - Category B. Eye Irritation - Category 2A. Sensitization - skin - Category 1. Aquatic toxicity - acute - Category 1.
CAS 84-61-7	Dicyclohexyl phthalate	40 - 55 %	Sensitization - skin - Category 1. Reproductive toxicant - Category 2. 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.

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

Following skin contact: Immediately remove all contaminated clothing. Wash with generous amount of water and soap. Always seek medical assistance if symptoms develop that are apparently due to exposure through skin.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. 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

Suspected of damaging fertility.
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:

no data available

Auto-ignition temperature: Danger of spontaneous combustion.

Suitable extinguishing media:

Water fog, foam, dry chemical powder, carbon dioxide

Extinguishing media which must not be used for safety reasons:

High power water jet, Halones.

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.
danger of dust explosion! Explosive when dry.
ATTENTION: re-ignition may occur.
In case of fire may be liberated: Benzoic acid, benzene, 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.

6. Accidental release measures

Personal precautions:

Eliminate all ignition sources if safe to do so.
Wear protective equipment. Keep unprotected people away.
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.
Avoid release to the environment.

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Methods for clean-up: Wet the material with water. Take up mechanically, placing in appropriate containers for disposal. Waste shall NOT be closed in tight.
Keep wet with water. Avoid generation of dust.
Final cleaning: To clean the floor and all objects contaminated by this material, use plenty of water..
Clean up with water before allowing to dry.

Additional information: Attention! danger of spontaneous combustion.

7. Handling and storage

Handling

Advices on safe handling: Do not weigh in storerooms.
Avoid contact with skin and eyes.
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.

Precautions against fire and explosion:
Keep away from sources of ignition. - No smoking. Use only spark proof tools.
Do not dry up the product. Avoid generation of dust. danger of dust explosion!
Do not weigh in storerooms. During the processing the peroxide and the accelerator have to be weight out separately and added. Do not mix with peroxide activators and reducing agents.
Use only explosion-proof equipment.
Electrical installations must be suitable for temperature class T 3.
Avoid shock and friction. Protect from: warmness

Storage

Requirements for storerooms and containers:
Keep container dry. Keep container in a well-ventilated place.
Keep container tightly closed in a cool place.
Do not seal.
Storage temperature: <77 °F. Protect from 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: Use only stainless steel to DIN 1.4751 specifications, or PVC, polyethylene or glass surfaced apparatuses.
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
7631-86-9	Silicon dioxide	USA: NIOSH: TWA	6 mg/m ³
		USA: OSHA: TWA	20 mppcf
		USA: OSHA: TWA	80 mg/m ³

Engineering controls

Provide adequate ventilation.

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

Use only stainless steel to DIN 1.4751 specifications, or PVC, polyethylene or glass surfaced apparatuses.

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 closed work clothing.
 Protective gloves according to OSHA Standard - 29 CFR: 1910.138.
 Glove material: Neoprene, Rubber (synthetic).
 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 P1 according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2.

General hygiene considerations:
 Avoid contact with skin and eyes. Do not breathe dust.
 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.
 Take off immediately all contaminated clothing.
 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: Form: Powder, free flowing
 Color: white

Odor: weak

Odor threshold: no data available

pH value: no data available

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Melting point/freezing point:	Decomposes before melting.
Initial boiling point and boiling range:	no data available
Flash point/flash point range:	no data available
Evaporation rate:	no data available
Flammability:	no data available
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: 131 °F 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.
Explosive properties:	not explosive
Ignition temperature:	Method: not applicable May form flammable dust-air mixture.
Bulk density:	at 68 °F: 620 - 650 kg/m ³
Additional information:	Contents of active oxygen: 3,3% Contents of Peroxide: 48,0 - 55,0%

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! Explosive when dry.
Conditions to avoid:	Avoid shock and friction. Protect from: warmth Do not dry up the product. Storage temperature: <77 °F. Protect from sunlight. Keep only in original container.
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 iron and copper .

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Hazardous decomposition products:

In case of fire may be liberated: Benzoic acid, benzene, carbon monoxide and carbon dioxide.

Thermal decomposition: SADT: 131 °F

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.

11. Toxicological information

Toxicological tests

Acute toxicity: LD50 Rat, oral: 78% dibenzoyl peroxide in water > 5000 mg/kg
 LC50 Rat, inhalative: 78% dibenzoyl peroxide in water > 24.3 mg/L/4h

Toxicological effects: Acute toxicity (oral): Lack of data.
 Acute toxicity (dermal): Lack of data.
 Acute toxicity (inhalative): Lack of data.
 Skin corrosion/irritation: Lack of data.
 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: Lack of data.
 Carcinogenicity: Lack of data.
 Reproductive toxicity: Reproductive toxicant - Category 2 = Suspected of damaging fertility.
 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: Lack of data.

Other information: dibenzoyl peroxide:
 Subchronic oral toxicity: NOAEL oral, Rat: 500 mg/kg/d
 Dicyclohexyl phthalate:
 Subchronic oral toxicity: NOAEL oral, Rat: 50 mg/kg/d
 developmental toxicity: NOAEL oral, Rat: 250 mg/kg/d
 effects on fertility: NOAEL oral, Rat: 16 - 21 mg/kg/d

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.
 Dibenzoyl peroxide (78%):
 Algae toxicity: EC50: 0,06 mg/L /72h.
 Bacterial toxicity: EC50: 35 mg/L.
 Daphnia toxicity: EC50 Daphnia magna: 0,11 mg/L /48 h.
 Fish toxicity: LC50: 0,06 mg/L /96 h.

Mobility in soil

Dibenzoyl peroxide (78%):
 Distribution coefficient Koc = 3,8 (71.6 °F)

Persistence and degradability

Further details: Dibenzoyl peroxide (78%):
 Abiotic degradation: 2,4 hours half-life time (122 °F)
 Biodegradable.

Additional ecological information

Volatile organic compounds (VOC):
 0 % by weight
 General information: Do not allow to penetrate into soil, waterbodies or drains.
 Avoid release to the environment.

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.

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14. Transport information

USA: Department of Transportation (DOT)

Identification numbers: UN3106
 Proper shipping name: UN 3106, ORGANIC PEROXIDE TYPE D, SOLID (dibenzoyl peroxide)
 DOT hazard class or division: 5.2
 PG: II
 Label codes: 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)
 IMDG: Class 5.2, Subrisk -
 Packing Group: -
 EmS: F-J, S-R
 Special provisions: 122, 274
 Limited quantities: 500 g
 EQ: 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

Air transport (IATA)

UN/ID number: UN 3106
 Proper shipping name: UN 3106, ORGANIC PEROXIDE TYPE D, SOLID (dibenzoyl peroxide)
 ICAO/IATA: Class 5.2
 Hazard: Organic peroxide
 EQ: E0
 Passenger Ltd.Qty.: Forbidden
 Passenger: Pack.Instr. 570 - Max. Net Qty/Pkg. 5 kg
 Cargo: Pack.Instr. 570 - Max. Net Qty/Pkg. 10 kg
 Special Provisioning: A20 A802
 ERG: 5L

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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.

Dicyclohexyl phthalate: TSCA: listed
 TSCA Inventory: listed
 TSCA HPVC: not listed

Silicon dioxide: TSCA Inventory: listed
 TSCA HPVC: not listed
 Carcinogen Status:
 IARC Rating: Group 3
 OSHA Carcinogen: not listed
 NTP Rating: not listed
 NIOSH Recommendations:
 Occupational Health Guideline: 0552

National regulations - Great Britain

Hazchem-Code: 1WE

16. Other information

Text for labeling: Contains 40 - 55 % Dibenzoyl peroxide, 40 - 55 % Dicyclohexyl phthalate. Safety data sheet available on request.

Hazard rating systems:



NFPA Hazard Rating:
 Health: 1 (Slight)
 Fire: 2 (Moderate)
 Reactivity: 3 (Serious)
 Precautions: OX (Material possesses oxidizing properties)

HMIS Version III Rating:
 Health: 1 (Slight) - Chronic effects
 Flammability: 2 (Moderate)
 Physical Hazard: 3 (Serious)
 Personal Protection: X = Consult your supervisor

HEALTH	*	1
FLAMMABILITY		2
PHYSICAL HAZARD		3
		X

Reason of change: Changes in section 14: IMDG 2015

Date of first version: 10/19/1994

Department issuing data sheet

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



SAFETY DATA SHEET

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

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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.