

1. Product and company identification

Product identifier

Trade name: 617P37 - Hardener Powder

This safety data sheet pertains to the following products:
617P37=0.150 = Härterpulver

Recommended use and restrictions on use

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

Initial supplier identifier

Company name: Otto Bock HealthCare Canada Ltd.

Street/POB-No.: 5470 Harvester Road

Postal Code, city: Burlington, ON L7L 5N5, CA
Canada

WWW: www.ottobock.ca

E-mail: info.canada@ottobock.com

Telephone: (800) 665-3327

Telefax: (800) 463-3659

Department responsible for information:

Mark Agro, Telephone: (800) 665-3327 (9 am - 5 pm)

Additional information:

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

Emergency phone number

COLLECT, Telephone: (613) 996-6666

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 20 °C and 101.3 kPa: solid

Form: Powder

Color: whitish

Odor: characteristic

Classification: Organic Peroxide D. Eye Irritation 2A. Sensitization - skin 1. Reproductive toxicity 1B.
Aquatic toxicity - acute 1. Aquatic toxicity - chronic 1.

Hazard symbols:



Signal word:

Danger

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 breathing dust/gas/mist/vapors.
- Avoid release to the environment.
- Wear protective gloves/protective clothing/eye protection.
- IF exposed or concerned: Get medical advice/attention.
- Take off contaminated clothing and wash it before reuse.
- Collect spillage.
- Store at temperatures not exceeding 30 °C/86 °F.

Regulatory status

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

Dust explosive

see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterisation: Powder-mixture.

Relevant ingredients:

CAS No.	Designation	Concentration	Classification
CAS 84-61-7	Dicyclohexyl phthalate	40 - 50 %	Sensitization - skin 1. Reproductive toxicity 1B. Aquatic toxicity - chronic 3.
CAS 94-36-0	Dibenzoyl peroxide	40 - 50 %	Organic Peroxide B. Eye Irritation 2A. Sensitization - skin 1. Aquatic toxicity - acute 1 (M-factor = 10). Aquatic toxicity - chronic 1 (M-factor = 10).

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.

Following skin contact: Wash with generous amount of water and soap. Take off immediately all contaminated clothing and wash it before reuse.
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 and effects, both 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: not self-igniting

Suitable extinguishing media:

Water spray jet, extinguishing powder, carbon dioxide.
In case of large fires: water spray jet, alcohol resistant foam

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.

Special protective equipment and precautions for fire-fighters:

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:	<p>Avoid exposure. Eliminate all ignition sources if safe to do so.</p> <p>Wear appropriate protective equipment. Take off immediately all contaminated clothing and wash it before reuse. Keep unprotected people away.</p> <p>Avoid generation of dust. Do not breathe dust. Avoid contact with eyes and skin.</p> <p>Provide adequate ventilation.</p> <p>In case of decomposition: Use filter type A (= against vapors of organic substances) according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2.</p>
Environmental precautions:	<p>Do not allow to penetrate into soil, waterbodies or drains. If necessary, notify appropriate authorities.</p>
Methods for clean-up:	<p>Take up mechanically, placing in appropriate containers for disposal. Waste shall NOT be closed in tight.</p> <p>Avoid generation of dust.</p>

7. Handling and storage

Handling

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

Storage

Requirements for storerooms and containers:	<p>Keep container dry. Keep container in a well-ventilated place.</p> <p>Keep container tightly closed in a cool place.</p> <p>Storage temperature: <30 °C. Protect from heat and direct sunlight.</p> <p>Keep only in original container.</p> <p>Storage according to local and national regulations.</p>
Hints on joint storage:	<p>Keep away from amines, acids, basic agents, heavy metals (e.g. from accelerating agents and drying materials).</p> <p>Avoid contact with iron and copper .</p> <p>Keep away from food, drink and animal feedingstuffs.</p>
Further details:	<p>Use only stainless steel to DIN 1.4751 specifications, or PVC, polyethylene or glass surfaced apparatuses.</p> <p>Danger of spontaneous combustion.</p>

8. Exposure controls / personal protection

Exposure guidelines

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
94-36-0	Dibenzoyl peroxide	Canada: OEL 8 hour	5 mg/m ³
		Canada: OEL TWA	5 mg/m ³
		Canada: VEMP	5 mg/m ³
		USA: ACGIH: TWA	5 mg/m ³
		USA: IDLH: TWA	1,500 mg/m ³
		USA: NIOSH: TWA	5 mg/m ³
		USA: OSHA: TWA	5 mg/m ³
7631-86-9	Silicon dioxide	USA: IDLH: TWA	3,000 mg/m ³
		USA: NIOSH: TWA	6 mg/m ³
		USA: OSHA: TWA	20 mppcf
		USA: OSHA: TWA	80 mg/m ³ (total dust)

Engineering controls

Provide adequate ventilation, and local exhaust as needed.

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 suitable protective clothing.

Protective gloves according to OSHA Standard - 29 CFR: 1910.138.

 Glove material: butyl caoutchouc (butyl rubber), Neoprene, fluoro rubber, nitrile rubber
 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:

Avoid shock and friction. 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.

Environmental exposure controls

Do not allow to enter into ground-water, surface water or drains.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:	Physical state at 20 °C and 101.3 kPa: solid Form: Powder Color: whitish
Odor:	characteristic
Odor threshold:	No data available
pH:	Not applicable
Melting point/freezing point:	not applicable
Initial boiling point and boiling range:	not applicable
Flash point/flash point range:	not applicable
Evaporation rate:	not applicable
Flammability:	Heating may cause a fire. not applicable
Explosion limits:	LEL (Lower Explosion Limit): not determined UEL (Upper Explosive Limit): not determined
Vapor pressure:	not applicable
Vapor density:	not applicable
Density:	at 20 °C: 1.23 g/cm ³
Water solubility:	at 20 °C: not determined
Partition coefficient: n-octanol/water:	not determined
Auto-ignition temperature:	not self-igniting
Thermal decomposition:	60 °C (SADT)
Viscosity, kinematic:	not applicable
Explosive properties:	Dust explosive
Bulk density:	at 20 °C: 650 kg/m ³
Additional information:	Contents of active oxygen: 3.2 - 3.4

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: 55 °C.
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 . Avoid contact with amines.

Hazardous decomposition products:

No hazardous decomposition products when regulations for storage and handling are observed.

Thermal decomposition:

60 °C (SADT)

11. Toxicological information

Toxicological tests

Toxicological effects:

The statements are derived from the properties of the single components. No toxicological data is available for the product as such.

Acute toxicity (oral): Based on available data, the classification criteria are not met.

Acute toxicity (dermal): Based on available data, the classification criteria are not met.

Acute toxicity (inhalative): Based on available data, the classification criteria are not met.

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/irritation: Eye Irritation 2A = Causes serious eye irritation.

Sensitisation to the respiratory tract: Lack of data.

Skin sensitisation: Sensitization - skin 1 = May cause an allergic skin reaction.

Germ cell mutagenicity/Genotoxicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity: Reproductive toxicity 1B = May damage the unborn child.

Effects on or via lactation: Lack of data.

Specific target organ toxicity (single exposure): Based on available data, the classification criteria are not met.

Specific target organ toxicity (repeated exposure): Based on available data, the classification criteria are not met.

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.

Package

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

14. Transport information

UN number

ADR/RID, IMDG, IATA-DGR:

UN 3106

UN proper shipping name

ADR/RID, IMDG, IATA-DGR:

UN 3106, ORGANIC PEROXIDE TYPE D, SOLID (dibenzoyl peroxide)

Transport hazard class(es)

ADR/RID: Class 5.2, Code: P1
IMDG: Class 5.2, Subrisk -
IATA-DGR: Class 5.2

Packing group

ADR/RID, IATA-DGR: not applicable
IMDG: -

Environmental hazards

Marine pollutant: yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No data available

USA: Department of Transportation (DOT)

Identification number: UN3106
Proper shipping name: UN 3106, ORGANIC PEROXIDE TYPE D, SOLID (dibenzoyl peroxide)
Hazard class or Division: 5.2
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



Canada: Transportation of Dangerous Goods (TDG)

UN Number: UN3106
Shipping name: UN 3106, ORGANIC PEROXIDE TYPE D, SOLID (dibenzoyl peroxide)
TDG class: 5.2
Packing group: II
Special provisions: 16, 38
Explosive limit and limited quantity index: 0.5 kg
Passenger carrying ship index: Forbidden
Passenger carrying road or rail index: 5 kg

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
Package - Instructions:	P520
Package - Provisions:	-
IBC - Instructions:	-
IBC - Provisions:	-
Tank instructions - IMO:	-
Tank instructions - UN:	-
Tank instructions - Provisions:	-
Stowage and handling:	Category D. SW1
Segregation:	SG35 SG36 SG72
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

15. Regulatory information

National regulations - Canada

Dicyclohexyl phthalate:	DSL: listed
Dibenzoyl peroxide:	DSL: listed
Silicon dioxide:	DSL: listed

National regulations - U.S. Federal Regulations

Dicyclohexyl phthalate: TSCA Inventory: listed
Dibenzoyl peroxide: TSCA Inventory: listed
Carcinogen Status:
IARC Rating: Group 3
OSHA Carcinogen: not listed
NTP Rating: not listed
NIOSH Recommendations:
Occupational Health Guideline: 0052
OSHA Process Safety Management: Threshold 7500 lbs.
Silicon dioxide: TSCA Inventory: listed
Carcinogen Status:
IARC Rating: Group 3
OSHA Carcinogen: not listed
NTP Rating: not listed
NIOSH Recommendations:
Occupational Health Guideline: 0552

National regulations - U.S. State Regulations

No data available

National regulations - EC member states

Further regulations, limitations and legal requirements:

Use restriction according to REACH annex XVII, no.: 30

16. Other information

Text for labeling: Contains 40 - 50 % Dicyclohexyl phthalate, 40 - 50 % Dibenzoyl peroxide.
Contains dibenzoyl peroxide and Dicyclohexyl phthalate.
For commercial user only.

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		

Abbreviations and acronyms:

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
 ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
 Aquatic toxicity - acute: Hazardous to the aquatic environment - acute
 Aquatic toxicity - chronic: Hazardous to the aquatic environment - chronic
 AS/NZS: Australian Standards/New Zealand Standards
 CAS: Chemical Abstracts Service
 CFR: Code of Federal Regulations
 CLP: Classification, Labelling and Packaging
 DIN: German Institute for Standardization
 DMEL: Derived minimal effect level
 DNEL: Derived no-effect level
 EC: European Community
 EC50: Effective Concentration 50%
 EmS: Emergency Response Procedures for Ships Carrying Dangerous Goods
 EN: European Standard
 EQ: Excepted quantities
 Eye Irritation: Eye irritation
 IATA: International Air Transport Association
 IATA-DGR: International Air Transport Association – Dangerous Goods Regulations
 IBC Code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
 IMDG Code: International Maritime Dangerous Goods Code
 IMO: International Maritime Organization
 LC50: Median lethal concentration
 LD50: Lethal dose 50%
 LEL: Lower Explosion Limit
 MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
 M-factor: Multiplication factor
 NOEC: No Observed Effect Concentration
 OECD: Organisation for Economic Co-operation and Development
 OEL: Occupational Exposure Limit Value
 Organic Peroxide: Organic peroxide
 OSHA: Occupational Safety and Health Administration
 PBT: Persistent, bioaccumulative and toxic
 PNEC: Predicted no-effect concentration
 PVC: Polyvinyl chloride
 REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
 Reproductive toxicity: Reproductive toxicity
 RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
 SADT: Self-Accelerating Decomposition Temperature
 Sensitization - skin: Skin sensitisation
 SVHC: Substance of very high concern
 TLV: Threshold Limit Value
 TRGS: Technical Rules for Hazardous Substances
 UN: United Nations
 vPvB: Very persistent and very bioaccumulative
 WEL: Workplace Exposure Limit
 WHMIS: Workplace Hazardous Materials Information System

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 8: Occupational exposure limit values

Date of first version: 19/10/1994

Department issuing data sheet

Contact person: see section 1: Department 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.