

1. Product and company identification

Product identifier

Trade name: 617P14 - Hardener Paste

This safety data sheet pertains to the following products:

617P14=0.150 = Härtepaste

617P14=0.500 = Härtepaste

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

General use: Curing agent 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

Department 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: Form: solid, pasty, thixotropic (68 °F)

Color: whitish

Odor: weak

Classification: Self Reactive - Category E. Eye Irritation - Category 2A. Sensitization - skin - Category 1. Specific Target Organ Toxicity (Repeated Exposure) - Category 2. Aquatic toxicity - acute - Category 1.

Hazard symbols:



Signal word:

Warning

Hazard statements:

- Heating may cause a fire.
- May cause an allergic skin reaction.
- Causes serious eye irritation.
- May cause damage to organs through prolonged or repeated exposure.
- Very toxic to aquatic life.

Precautionary statements:

- Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- Keep only in original container.
- Ground/bond container and receiving equipment.
- Avoid release to the environment.
- Wear protective gloves/protective clothing/eye protection.
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- IF exposed or concerned: Get medical advice/attention.
- Store in a well-ventilated place. Keep cool.
- Dispose of contents/container to hazardous or special waste collection point.

Regulatory status

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

Hazards not otherwise classified

see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: Paste: Dibenzoyl peroxide 50%, solvent mixture, contains zinc-carboxylate and non-ionic surfactant.

Relevant ingredients:

CAS No.	Designation	Concentration	Classification
CAS 94-36-0	Dibenzoyl peroxide	45 - 55 %	Organic Peroxide - Category B. Eye Irritation - Category 2A. Sensitization - skin - Category 1. Aquatic toxicity - acute - Category 1 (M-factor = 10).
CAS 111-46-6	Diethylene glycol	5 - 10 %	Acute Toxicity - oral - Category 4. Specific Target Organ Toxicity (Repeated Exposure) - Category 2.
CAS 105-76-0	Dibutyl maleate	5 - 10 %	Sensitization - skin - Category 1. Specific Target Organ Toxicity (Repeated Exposure) - Category 2.
CAS 557-05-1	Zinc distearate	2.5 - 5 %	Aquatic toxicity - acute - Category 1.
CAS 128-37-0	3,5-Di-tert-butyl-4-hydroxytoluene	0.2 %	Aquatic toxicity - acute - Category 1. Aquatic toxicity - chronic - Category 1.

4. First aid measures

General information: Seek medical attention if problems persist.

In case of inhalation:	Move victim to fresh air, put at rest and loosen restrictive clothing. Keep airway open. If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
Following skin contact:	Wash with generous amount of water and soap. In case of skin irritation, consult a physician. Immediately remove all contaminated clothing. Take off immediately all contaminated clothing and wash it before reuse.
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. Afterwards, consult an ophthalmologist immediately.
After swallowing:	Rinse mouth with water. Never give anything by mouth to an unconscious person. If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label. In case of vomiting, position victim on their side.

Most important symptoms/effects, acute and delayed

Causes serious eye irritation.
May cause an allergic skin reaction.
May cause damage to organs through prolonged or repeated exposure.
After inhaling and vomiting danger of lung oedema.
After ingestion, Diethylene glycol:
Nausea, vomiting, diarrhea, headache, dizziness, liver damage, damage of kidneys.

Information to physician

Treat symptomatically.
consider the need for health surveillance.
After inhaling and vomiting danger of lung oedema.
Call a POISON CENTER.

5. Fire fighting measures

Flash point/flash point range:	not available
Auto-ignition temperature:	danger of spontaneous combustion.
Suitable extinguishing media:	Water spray jet, alcohol resistant foam, dry chemical powder, carbon dioxide Prevent subsequent re-ignition with abundant quantities of water.
Extinguishing media which must not be used for safety reasons:	Strong water jet.

Specific hazards arising from the chemical

ATTENTION: re-ignition may occur. Decomposition under heating. Product enhances combustion.
In case of fire may be liberated: carbon monoxide and carbon dioxide, benzoic acid, benzene, Biphenyl phenyl benzoate.

Protective equipment and precautions for firefighters:	Wear self-contained positive pressure breathing apparatus and full firefighting protective clothing.
Additional information:	Use fine water spray to cool endangered containers. In case of fire and/or explosion do not breathe fumes. Flammability Class: NFPA 2 Do not allow water used to extinguish fire to enter drains, ground or waterways. Remove persons to safety.

6. Accidental release measures

Personal precautions:	Eliminate all ignition sources if safe to do so. Provide adequate ventilation. Wear appropriate protective equipment. Keep unprotected people away. Avoid contact with skin, eyes, and clothing. Do not breathe vapors.
Environmental precautions:	Do not allow to enter drains, basements or pits.
Methods for clean-up:	Take up mechanically, placing in appropriate containers for disposal. Do not keep the container sealed. Cover remnants with an inert absorption agent (eg. Vermiculit). Keep wetted with water. Wash spill area with plenty of water. Danger of spontaneous combustion.

7. Handling and storage

Handling

Advices on safe handling:	Do not weigh in storerooms. Do not mix with peroxide activators and reducing agents. During the processing the peroxide and the accelerator have to be weight out separately and added. When using do not eat, drink or smoke. Provide adequate ventilation, and local exhaust as needed. Do not breathe vapors. Avoid contact with skin and eyes. Wash hands before breaks and after work. Separate storage of work clothes.
Precautions against fire and explosion:	Use only spark proof tools. Use only explosion-proof equipment. Keep away from sources of ignition - No smoking. Avoid shock and friction.

Storage

Requirements for storerooms and containers:	Keep only in the original container in a cool, well-ventilated place. Do not keep the container sealed. Do not allow to dry. Store carefully closed containers upright to prevent any leaks. Avoid temperatures exceeding 77 °F. Protect from heat and direct sunlight. Storage according to local and national regulations.
Hints on joint storage:	Keep/Store away from clothing/rust, chemicals/combustible materials. Keep away from amines, acids, basic agents, heavy metals (e.g. from accelerating agents and drying materials). Keep away from food, drink and animal feedingstuffs.
Further details:	Electrical installations must be suitable for temperature class T 3.

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 USA: IDLH: TWA USA: NIOSH: TWA USA: OSHA: TWA	5 mg/m ³ 1,500 mg/m ³ 5 mg/m ³ 5 mg/m ³
557-05-1	Zinc distearate	USA: ACGIH: TWA USA: ACGIH: TWA USA: NIOSH: TWA USA: NIOSH: TWA USA: OSHA: TWA USA: OSHA: TWA	10 mg/m ³ (inhalable fraction) 3 mg/m ³ (respirable fraction) 10 mg/m ³ (inhalable fraction) 5 mg/m ³ (respirable fraction) 15 mg/m ³ (total dust) 5 mg/m ³ (respirable fraction)
128-37-0	3,5-Di-tert-butyl-4-hydroxytoluene	USA: ACGIH: TWA USA: NIOSH: TWA	2 mg/m ³ (inhalable fraction and vapor) 10 mg/m ³

Engineering controls

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.
Provide adequate ventilation.
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: rubber or Neoprene
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.
Use filter type A (= against vapors of organic substances) according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2.

General hygiene considerations:
Keep away from sources of ignition - No smoking.
Use only spark proof tools.
When using do not eat, drink or smoke.
Do not breathe vapors. Avoid contact with skin and eyes. Wash hands before breaks and after work.
Safety shower and eye wash station should be easily accessible to the work area.

Environmental exposure controls

Refer to 6.: Section "Environmental precautions".

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:	Form: solid, pasty, thixotropic (68 °F) Color: whitish
Odor:	weak
Odor threshold:	No data available
pH:	No data available
Melting point/freezing point:	not available (Decomposition)
Initial boiling point and boiling range:	not available (Decomposition)
Flash point/flash point range:	not 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:	No data available
Water solubility:	at 68 °F: insoluble
Partition coefficient: n-octanol/water:	3.38 log P(o/w) Based on the n-octanol/water partition coefficient significant accumulation in organisms is not expected.
Auto-ignition temperature:	danger of spontaneous combustion.
Thermal decomposition:	SADT: 122 °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:	Product is not explosive.
Additional information:	Contents of active oxygen: 3,31% Contents of Peroxide: 50%

10. Stability and reactivity

Reactivity:	Heating may cause a fire. 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.
Chemical stability:	Stable under recommended storage conditions. (Refer to section 7, storage temperature: <77 °F)
Possibility of hazardous reactions:	Polymerisation will not occur. In case of heating above recommended storage temperature, bursting danger of cans.
Conditions to avoid:	Avoid temperatures exceeding 77 °F. Protect from heat and direct sunlight. Do not dry up the product. 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.

Incompatible materials: Danger of a hazardous self-accelerating decomposing reaction.

Hazardous decomposition products:

In case of fire may be liberated: carbon monoxide and carbon dioxide, benzoic acid, benzene, Biphenyl phenyl benzoate.

Thermal decomposition: SADT: 122 °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 > 5,000 mg/kg
LC50 Rat, inhalative: 78% dibenzoyl peroxide in water 24.3 mg/m³ dust

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): Lack of data.

Acute toxicity (dermal): Lack of data.

Acute toxicity (inhalative): Lack of data.

Skin corrosion/irritation: Lack of data.

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: Lack of data.

Carcinogenicity: Lack of data.

Reproductive toxicity: Lack of data.

Effects on or via lactation: Lack of data.

Specific target organ toxicity (single exposure): Lack of data.

Specific target organ toxicity (repeated exposure): Specific Target Organ Toxicity (Repeated Exposure) -

Category 2 = May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard: Lack of data.

Other information: Dibenzoyl peroxide:
NOAEL: 1000 mg/kg/d (test duration: 29 days)

NOAEL oral: 500 mg/kg/d

Mutagenicity: not a mutagen (Ames-Test)

Diethylene glycol:

After absorption of large quantities: fatigue, CNS disorders

Toxic effect on kidneys. Toxic effect on liver.

Not known to cause sensitization. (guinea pig).

Bacterial mutagenicity: negative (Salmonella typhimurium).

Symptoms

After inhaling and vomiting danger of lung oedema.

In case of ingestion: Diethylene glycol:

Nausea, vomiting, diarrhea, headache, dizziness, liver damage, damage of kidneys.

After contact with skin: Dibenzoyl peroxide: mild irritant

12. Ecological information

Ecotoxicity

Aquatic toxicity:

Very toxic to aquatic life.

Dibenzoyl peroxide (78%):

Algae toxicity: EC50: 0,06 mg/L /72h.

Bacterial toxicity: EC50: 35 mg/L.

Daphnia toxicity: EC50 Daphnia magna (Big water flea): 0,11 mg/L /48 h.

Fish toxicity: LC50: 0,06 mg/L /96 h.

toxicity aquatic plants: EC50: 0.83 mg/L/72h

Dibutyl maleate:

Algae toxicity:

IC50 Desmodesmus subspicatus (green algae): 6,2 mg/L/72h.

Daphnia toxicity:

EC50 Daphnia magna (Big water flea): 21 mg/L/48h. (OECD 202)

Fish toxicity:

LC50 Oncorhynchus mykiss: 1,2 mg/L/96 h (OECD 203)

Bacteria toxicity:

Pseudomonas putida EC10: 1003 mg/L/6 h (IUCLID)

Mobility in soil

Dibenzoyl peroxide (78%):

Distribution coefficient Koc = 3,8 (71.6 °F)

Dibutyl maleate:

Distribution coefficient log P(o/w) = 3,38

Persistence and degradability

Further details:

Dibenzoyl peroxide (78%):

Abiotic degradation: 2,4 hours half-life time (122 °F)

Dibenzoyl peroxide: Product is readily biodegradable. (closed bottle test)

Dibutyl maleate:

Product is readily biodegradable.

zinc-carboxylate:

Product is biodegradable.

Additional ecological information

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.

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

Package

Recommendation: Dispose of waste according to applicable legislation.

14. Transport information

UN number

ADR/RID, IMDG, IATA-DGR:

UN 3108

UN proper shipping name

ADR/RID, IMDG, IATA-DGR:

UN 3108, ORGANIC PEROXIDE TYPE E, 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:

UN3108

Proper shipping name:

UN 3108, ORGANIC PEROXIDE TYPE E, 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:

10 kg

Quantity limitations – Cargo only:

25 kg

Vessel stowage – Location:

D

Vessel stowage – Other:

12, 25, 52, 53



Sea transport (IMDG)

UN number:	UN 3108
Proper shipping name::	UN 3108, ORGANIC PEROXIDE TYPE E, 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. 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 3108
Proper shipping name::	UN 3108, ORGANIC PEROXIDE TYPE E, 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. 10 kg
Cargo Aircraft only:	Pack.Instr. 570 - Max. Net Qty/Pkg. 25 kg
Special Provisions:	A20 A802
Emergency Response Guide-Code (ERG):	5L

15. Regulatory information

National regulations - U.S. Federal Regulations

Product:	SARA Title III - Hazard Classes: - Acute Health Hazard - Fire Hazard
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.
Diethylene glycol:	TSCA Inventory: listed Clean Air Act: CAA SOCM Chemical: yes
Dibutyl maleate:	TSCA Inventory: listed
Zinc distearate:	TSCA Inventory: listed NIOSH Recommendations: Occupational Health Guideline: 0676
3,5-Di-tert-butyl-4-hydroxytoluene:	TSCA Inventory: listed Carcinogen Status: IARC Rating: Group 3 OSHA Carcinogen: not listed NTP Rating: not listed NIOSH Recommendations: Occupational Health Guideline: 0246

National regulations - U.S. State Regulations

No data available

National regulations - Canada

Dibenzoyl peroxide:	DSL: listed
Diethylene glycol:	DSL: listed
Dibutyl maleate:	DSL: listed
Zinc distearate:	DSL: listed
3,5-Di-tert-butyl-4-hydroxytoluene:	DSL: listed

National regulations - Great Britain

Hazchem-Code: 1W

16. Other information

Text for labeling: Contains 45 - 55 % Dibenzoyl peroxide, 5 - 10 % Diethylene glycol, 5 - 10 % Dibutyl maleate, 2.5 - 5 % Zinc distearate, 0.2 % 3,5-Di-tert-butyl-4-hydroxytoluene.
Contains Dibenzoyl peroxide, Diethylene glycol and Dibutyl maleate.

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:

Acute Toxicity: Acute toxicity
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
CNS: Central Nervous System
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
IC50: Inhibition Concentration 50%
IMDG Code: International Maritime Dangerous Goods Code
IMO: International Maritime Organization
LC50: Median lethal concentration
LD50: Lethal dose 50%
log P(o/w): Partition coefficient: octanol/water
MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
M-factor: Multiplication factor
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
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
SADT: Self-Accelerating Decomposition Temperature
Self Reactive: Self-reactive substances and mixtures
Sensitization - skin: Skin sensitisation
STOT RE: Specific target organ toxicity - repeated exposure
TLV: Threshold Limit Value
TRGS: Technical Rules for Hazardous Substances
UN: United Nations
vPvB: Very persistent and very bioaccumulative
WEL: Workplace Exposure Limit

Reason of change:

Changes in section 2: Classification

Date of first version:

10/19/1994

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.