

1. Product and company identification

Product identifier

Trade name: 617P5 - EP Hardener for Orthopox

This safety data sheet pertains to the following products:

617P5=0.26 = EP Härter für Orthopox

617P5=0.7 = EP Härter für Orthopox

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

General use: Adhesive for orthopedic procedures.
Curing agent for bisphenol epoxy resins.
Reserved for industrial and professional use.

Identified uses: Compound material

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: Physical state at 68 °F and 101.3 kPa: liquid

Color: colorless up to light yellow

Odor: Amine odor

Classification: Acute Toxicity - oral - Category 4. Acute Toxicity - dermal - Category 4.
Skin Corrosion - Category 1B. Eye Damage - Category 1. Sensitization - skin - Category 1. Reproductive toxicant - Category 2.
Specific Target Organ Toxicity (Repeated Exposure) - Category 1.
Aquatic toxicity - chronic - Category 3.

Hazard symbols:



Signal word:

Danger

Hazard statements:

Harmful if swallowed.
Harmful in contact with skin.
Causes severe skin burns and eye damage.
May cause an allergic skin reaction.
Suspected of damaging fertility. Suspected of damaging the unborn child.
Causes damage to organs through prolonged or repeated exposure.
Harmful to aquatic life with long lasting effects.

Precautionary statements:

Obtain special instructions before use.
Do not breathe mist/spray.
Wear protective gloves/protective clothing/eye protection/face protection.
IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/or shower.
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Immediately call a POISON CENTER/doctor.

Regulatory status

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

Hazards not otherwise classified

Special danger of slipping by leaking/spilling product.
see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: Hardener component based on amines.

Relevant ingredients:

CAS No.	Designation	Concentration	Classification
CAS 2855-13-2	3-Aminomethyl-3,5,5-trimethylcyclohexylamine	25 - 50 %	Acute Toxicity - oral - Category 4. Acute Toxicity - dermal - Category 4. Skin Corrosion - Category 1B. Eye Damage - Category 1. Sensitization - skin - Category 1A. Aquatic toxicity - chronic - Category 3.
CAS 140-31-8	2-Piperazin-1-ylethylamine	25 - 46 %	Acute Toxicity - oral - Category 4. Acute Toxicity - dermal - Category 3. Skin Corrosion - Category 1B. Sensitization - skin - Category 1. Reproductive toxicant - Category 2. Specific Target Organ Toxicity (Repeated Exposure) - Category 1. Aquatic toxicity - chronic - Category 3.
CAS 25620-58-0	Trimethylhexane-1,6-diamine	10 - 25 %	Acute Toxicity - oral - Category 4. Skin Corrosion - Category 1C. Eye Damage - Category 1. Sensitization - skin - Category 1. Aquatic toxicity - chronic - Category 3.
CAS 9046-10-0	Poly-(oxypropylendiamine)	10 - 25 %	Skin Corrosion - Category 1C. Eye Damage - Category 1. Aquatic toxicity - chronic - Category 3.
CAS 1477-55-0	m-Phenylenebis(methylamine)	10 - 25 %	Acute Toxicity - oral - Category 4. Acute Toxicity - inhalative - Category 4. Skin Corrosion - Category 1B. Eye Damage - Category 1. Sensitization - skin - Category 1B. Aquatic toxicity - chronic - Category 3.

4. First aid measures

General information:	First aider: Pay attention to self-protection! Immediately call a POISON CENTER/doctor. Do not effect a mouth-to-mouth resuscitation. Take off immediately all contaminated clothing and wash it before reuse.
In case of inhalation:	If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical attention. If unconscious place in recovery position and seek medical advice.
Following skin contact:	Immediately clean with water and soap followed by thorough rinsing. In case of skin reactions, consult a physician.
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 seek the immediate attention of an ophthalmologist.
After swallowing:	Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person. Do not induce vomiting. In case of vomiting, position victim on their side. Immediately get medical attention.

Most important symptoms/effects, acute and delayed

Causes severe skin burns and eye damage. May cause an allergic skin reaction. Harmful if swallowed or in contact with skin.

Information to physician

Treat symptomatically.

Symptoms of poisoning may develop several hours following exposure. Victim should be under medical observation for at least 48 hours after exposure.

5. Fire fighting measures

Flash point/flash point range:

No data available

Auto-ignition temperature:

No data available

Suitable extinguishing media:

Water spray jet, 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

May form dangerous gases and vapors in case of fire.

Furthermore, there may develop: nitrogen oxides (NO_x), Carbon monoxide and carbon dioxide.

Protective equipment and precautions for firefighters:

Use a breathing apparatus independent of the ambient air (isolated apparatus) and a full protection outfit (suit) against chemicals.

Additional information:

Heating will lead to pressure increase: Danger of bursting and explosion. Keep containers cool with water spray.

In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.

Do not allow fire water to penetrate into surface or ground water.

Fire residuals and contaminated extinguishing water must be disposed of in accordance with the regulations of the local authorities.

6. Accidental release measures

Personal precautions:

Ensure self-protection. Avoid exposure. Do not breathe mist/vapors/spray. Avoid contact with the substance.

If possible, eliminate leakage. Provide adequate ventilation.

Wear appropriate protective equipment. Take off immediately all contaminated clothing and wash it before reuse. Keep unprotected people away.

Environmental precautions:

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

If necessary, notify appropriate authorities.

Methods for clean-up:

Isolate leaked material using non-flammable absorption agent (e.g. sand, earth, vermiculit, diatomaceous earth) and collect it for disposal in appropriate containers in accordance with the local regulations (see section 13).

In case of greater quantities: Collect mechanically (use only explosion-proof equipment when pumping out).

Never return spills in original containers for re-use.

Additional information:

Special danger of slipping by leaking/spilling product.

7. Handling and storage

Handling

Advices on safe handling: Obtain special instructions before use.
Provide adequate ventilation, and local exhaust as needed. Do not breathe mist/vapors/spray. Do not get in eyes, on skin, or on clothing. Wear appropriate protective equipment.
Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Take off immediately all contaminated clothing and wash it before reuse.
Work place should be equipped with a shower and an eye rinsing apparatus.

Precautions against fire and explosion:
Keep away from heat.
When handling larger quantities, take precautionary measures against electrostatic charging.

Storage

Requirements for storerooms and containers:
Keep container tightly closed and in a well-ventilated place.
Keep container dry. Keep only in the original container.
Protect from heat and direct sunlight.
Store containers in upright position.

Hints on joint storage: Keep away from food, drink and animal feedingstuffs.
Do not store together with: Strong oxidizing agents

8. Exposure controls / personal protection

Exposure guidelines

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
1477-55-0	m-Phenylenebis (methylamine)	USA: ACGIH: Ceiling	0.018 ppm (may be absorbed through the skin)
		USA: NIOSH: Ceiling	0.1 mg/m ³ (may be absorbed through the skin)

Engineering controls

Provide for good ventilation or exhaust system or work with completely self-contained equipment.
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 and shoes.
Protective gloves according to OSHA Standard - 29 CFR: 1910.138.
Glove material: nitrile rubber-Layer thickness: 0,35 mm
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. In case of inadequate ventilation wear respiratory protection. The filter class must be suitable for the maximum contaminant concentration (gas/vapor/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used. Recommendation: Use filter type A (= against vapors of organic substances) according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2.

General hygiene considerations:
Obtain special instructions before use. Do not breathe mist/vapors/spray. Do not get in eyes, on skin, or on clothing.
Take off immediately all contaminated clothing and wash it before reuse.
Do not eat, drink or smoke when using this product.
Wash hands thoroughly after handling.
Work place should be equipped with a shower and an eye rinsing apparatus.

Environmental exposure controls

Refer to 6.: Section "Environmental precautions".

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:	Physical state at 68 °F and 101.3 kPa: liquid Color: colorless up to light yellow
Odor:	Amine odor
Odor threshold:	No data available
pH:	No data available
Melting point/freezing point:	No data available
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:	No data available
Solubility:	No data available
Partition coefficient: n-octanol/water:	-1.48 log P(o/w) (2-Piperazin-1-ylethylamine) Based on the n-octanol/water partition coefficient accumulation in organisms is not expected. 0.18 - 0.43 log P(o/w) (m-Phenylenebis(methylamine)) Based on the n-octanol/water partition coefficient accumulation in organisms is not expected. 1.34 log P(o/w) (Polyoxypropylene diamine) Based on the n-octanol/water partition coefficient significant accumulation in organisms is not expected.
Auto-ignition temperature:	No data available
Thermal decomposition:	No data available
Additional information:	No data available

10. Stability and reactivity

Reactivity:	Refer to subsection "Possibility of hazardous reactions".
Chemical stability:	Stable under recommended storage conditions.
Possibility of hazardous reactions:	No dangerous reactions with proper and specified storage and handling
Conditions to avoid:	Keep away from heat sources, sparks and open flames. Protect from direct sunlight.
Incompatible materials:	Strong oxidizing agents.
Hazardous decomposition products:	No decomposition when used properly.
Thermal decomposition:	No data available

11. Toxicological information

Toxicological tests

Toxicological effects:	<p>The statements are derived from the properties of the single components. No toxicological data is available for the product as such.</p> <p>Acute toxicity (oral): Acute Toxicity - oral - Category 4 = Harmful if swallowed. ATEmix (calculated): 863.1 mg/kg</p> <p>Acute toxicity (dermal): Acute Toxicity - dermal - Category 4 = Harmful in contact with skin. ATEmix (calculated): 1710.8 mg/kg</p> <p>Acute toxicity (inhalative): Based on available data, the classification criteria are not met. ATEmix (calculated): 77 mg/L</p> <p>Skin corrosion/irritation: Skin Corrosion - Category 1B = Causes severe skin burns and eye damage.</p> <p>Serious eye damage/irritation: Eye Damage - Category 1 = Causes serious eye damage.</p> <p>Sensitisation to the respiratory tract: Lack of data.</p> <p>Skin sensitisation: Sensitization - skin - Category 1 = May cause an allergic skin reaction.</p> <p>Germ cell mutagenicity/Genotoxicity: Lack of data.</p> <p>Carcinogenicity: Lack of data.</p> <p>Reproductive toxicity: Reproductive toxicant - Category 2 = Suspected of damaging fertility. Suspected of damaging the unborn child.</p> <p>Effects on or via lactation: Lack of data.</p> <p>Specific target organ toxicity (single exposure): Lack of data.</p> <p>Specific target organ toxicity (repeated exposure): Specific Target Organ Toxicity (Repeated Exposure) - Category 1 = Causes damage to organs through prolonged or repeated exposure.</p> <p>Aspiration hazard: Lack of data.</p>
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Other information: Information about 3-Aminomethyl-3,5,5-trimethylcyclohexylamine (CAS No. 2855-13-2):
LD50 oral, Rat: 1,030 mg/kg/bw

Information about 2-Piperazin-1-ylethylamine (CAS No. 140-31-8):
LD50 oral, Rat: > 1,000 mg/kg/bw
LD50 dermal, Rabbit: 866 mg/kg/bw

Information about Trimethylhexane-1,6-diamine (CAS No. 25620-58-0):
LD50 oral, Rat: 910 mg/kg/bw

Information about Polyoxypipeline diamine (CAS No. 9046-10-0):
LD50 oral, Rat: 2,885 mg/kg
LD50 dermal, Rabbit: 2,980 mg/kg

Information about m-Phenylenebis(methylamine) (CAS No. 1477-55-0):
LD50 oral, Rat: 930 mg/kg/bw
LC50 inhalative (vapors), Rat: 3.89 mg/L/1h
LC50 inhalative (vapors), Rat: 2.4 mg/L/4h
LC50 inhalative (vapors), Rat: (female) 0.8 mg/L/4h
LD50 dermal, Rabbit: 2,000 mg/kg/bw

Symptoms

Reduced fetal weight, increase in skeletal deformities

In case of inhalation:
Has a strong irritation effect on respiratory tract and lungs. Symptoms may occur with delay.

In case of ingestion: Burns in the mouth, pharynx, oesophagus, and gastrointestinal tract. stomachache.

After contact with skin:
Prolonged or repeated contact with skin or mucous membrane result in irritation symptoms such as redness, blistering, dermatitis, etc.

Pain.

After eye contact: Upon direct contact with eyes may cause burning, tearing, redness.

12. Ecological information

Ecotoxicity

Aquatic toxicity: Harmful to aquatic life with long lasting effects.

Information about 3-Aminomethyl-3,5,5-trimethylcyclohexylamine (CAS No. 2855-13-2):
Daphnia toxicity: EC50 17.4 mg/L/48h

Information about 2-Piperazin-1-ylethylamine (CAS No. 140-31-8):
Fish toxicity: LC50 2,190 mg/L/96h

Mobility in soil

No data available

Persistence and degradability

Further details: No data available

Additional ecological information

AOX reference: Product does not contain organically bound halogen (AOX).

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

13. Disposal considerations

Product

Recommendation: Do not dispose of with household waste.
Special waste. Dispose of waste according to applicable legislation.
Do not allow to enter into ground-water, surface water or drains.

Package

Recommendation: Dispose of waste according to applicable legislation.
Handle contaminated packages in the same way as the substance itself.

14. Transport information

UN number

ADR/RID, IMDG, IATA-DGR:

UN 2735

UN proper shipping name

ADR/RID, IMDG, IATA-DGR:

UN 2735, POLYAMINES, LIQUID, CORROSIVE, N.O.S.
(3-Aminomethyl-3,5,5-trimethylcyclohexylamine, 2-Piperazin-1-ylethylamine)

Transport hazard class(es)

ADR/RID: Class 8, Code: C7

IMDG: Class 8, Subrisk -

IATA-DGR: Class 8



Packing group

ADR/RID, IMDG, IATA-DGR:

II

Environmental hazards

Marine pollutant: no

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: UN2735

Proper shipping name: UN 2735,
AMINES, LIQUID, CORROSIVE, N.O.S. or POLYAMINES,
LIQUID, CORROSIVE, N.O.S.
(3-Aminomethyl-3,5,5-trimethylcyclohexylamine,
2-Piperazin-1-ylethylamine)

Hazard class or Division: 8

Packing Group: II

Labels: 8

Symbols: G

Special Provisions: B2, IB2, T11, TP1, TP27

Packaging – Exceptions: 154

Packaging – Non-bulk: 202

Packaging – Bulk: 242

Quantity limitations – Passenger aircraft / rail: 1 L

Quantity limitations – Cargo only: 30 L

Vessel stowage – Location: A

Vessel stowage – Other: 52



Sea transport (IMDG)

UN number: UN 2735

Proper shipping name: UN 2735, POLYAMINES, LIQUID, CORROSIVE, N.O.S.
(3-Aminomethyl-3,5,5-trimethylcyclohexylamine, 2-Piperazin-1-ylethylamine)

Class or division, Subsidiary risk: Class 8, Subrisk -

Packing Group: II

EmS: F-A, S-B

Special Provisions: 274

Limited quantities: 1 L

Excepted quantities: E2

Package - Instructions: P001

Package - Provisions: -

IBC - Instructions: IBC02

IBC - Provisions: -

Tank instructions - IMO: -

Tank instructions - UN: T11

Tank instructions - Provisions: TP1, TP27

Stowage and handling: Category A.

Segregation: SG35

Properties and observations: Colourless to yellowish liquids or solutions with a pungent odour. Miscible with or soluble in water. When involved in a fire, evolve toxic gases. Corrosive to most metals, especially to copper and its alloys. React violently with acids. Cause burns to skin, eyes and mucous membranes.

Marine pollutant: no

Segregation group: 18

Air transport (IATA)

UN/ID number:	UN 2735
Proper shipping name::	UN 2735, POLYAMINES, LIQUID, CORROSIVE, N.O.S. (3-Aminomethyl-3,5,5-trimethylcyclohexylamine, 2-Piperazin-1-ylethylamine)
Class or division, Subsidiary risk:	Class 8
Packing Group:	II
Hazard label:	Corrosive
Excepted Quantity Code:	E2
Passenger and Cargo Aircraft: Ltd.Qty.:	Pack.Instr. Y840 - Max. Net Qty/Pkg. 0.5 L
Passenger and Cargo Aircraft:	Pack.Instr. 851 - Max. Net Qty/Pkg. 1 L
Cargo Aircraft only:	Pack.Instr. 855 - Max. Net Qty/Pkg. 30 L
Special Provisions:	A3 A803
Emergency Response Guide-Code (ERG):	8L

Further information

Make sure that persons transporting the product know what to do in case of an accident or leakage.

15. Regulatory information

National regulations - U.S. Federal Regulations

Product:	TSCA: All ingredients are listed or exempt from listing.
m-Phenylenebis(methylamine):	Carcinogen Status: IARC Rating: Group 2B OSHA Carcinogen: not listed NTP Rating: not listed
	Clean Air Act: CAA Accidental Release Prevention: Threshold 10000 lbs. / Basis for listing = g CAA Hazardous Air Pollutants: yes CAA Ozone Depleting Chemicals:-- / Depletion potential -- CAA SOCM1 Chemical: yes
	Clean Water Act: CWA Hazardous Substances: RQ 1000 lbs. CWA Priority Pollutants: yes
	Other Environmental Laws: CERCLA: RQ 100 lbs. Marine Pollutant: listed as pollutant. RCRA Hazardous Wastes: Code U394 RCRA Groundwater Monitoring: Methods 8100, 8270 / PQL 200, 10 SARA Title III, Section 302, EHS: TPQ 500/10000 lbs. / RQ 100 lbs. SARA Title III - Section 313, Toxic Release: Conc. 1.0% / Threshold Standard
	NIOSH Recommendations: Occupational Health Guideline: 0671 OSHA Process Safety Management: Threshold 2500 lbs.

National regulations - U.S. State Regulations

m-Phenylenebis(methylamine): Idaho Air Pollutant List: listed
Massachusetts Haz. Substance Codes:
4
Minnesota Haz. Substance: listed
Pennsylvania Haz. Substance Code: -
Washington Air Contaminant: listed

16. Other information

Text for labeling:

Contains 25 - 50 % 3-Aminomethyl-3,5,5-trimethylcyclohexylamine, 25 - 46 %
2-Piperazin-1-ylethylamine, 10 - 25 % Trimethylhexane-1,6-diamine, 10 - 25 %
Poly-(oxypropylendiamine), 10 - 25 % m-Phenylenebis(methylamine). Safety data sheet
available on request.

Contains: 3-Aminomethyl-3,5,5-trimethylcyclohexylamine, 2-Piperazin-1-ylethylamine,
Trimethylhexane-1,6-diamine, Polyoxypropylene diamine.

Hazard rating systems:



NFPA Hazard Rating:

Health: 3 (Serious)
Fire: 1 (Slight)
Reactivity: 0 (Minimal)

HMIS Version III Rating:

Health: 3 (Serious) - Chronic effects
Flammability: 1 (Slight)
Physical Hazard: 0 (Minimal)
Personal Protection: X = Consult your supervisor

HEALTH	*	3
FLAMMABILITY		1
PHYSICAL HAZARD		0
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
AOX: Adsorbable Organic Halogens
Aquatic toxicity - chronic: Hazardous to the aquatic environment - chronic
AS/NZS: Australian Standards/New Zealand Standards
Bw: Body weight
CAS: Chemical Abstracts Service
CFR: Code of Federal Regulations
CLP: Classification, Labelling and Packaging
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 Damage: Eye damage
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%
log P(o/w): Partition coefficient: octanol/water
MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
OEL: Occupational Exposure Limit Value
OSHA: Occupational Safety and Health Administration
PBT: Persistent, bioaccumulative and toxic
PNEC: Predicted no-effect concentration
Reproductive toxicant: Reproductive toxicity
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
Sensitization - skin: Skin sensitisation
Skin Corrosion: Skin corrosion
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: **General revision**

Date of first version: **1/18/2018**

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.