

1. Product and company identification

Product identifier

Trade name: 617HG5 - OrthoEpoX GreenLine

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

General use: For orthopedic procedures, for producing molds.

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

Form: viscous

Odor: No data available

Classification: Acute Toxicity - oral - Category 4. Skin Irritation - Category 2. Eye Damage - Category 1. Sensitization - skin - Category 1. Germ cell mutagenicity - Category 2. Aquatic toxicity - chronic - Category 3.

Hazard symbols:



Signal word: **Danger**

Hazard statements:

- Harmful if swallowed.
- Causes skin irritation.
- May cause an allergic skin reaction.
- Causes serious eye damage.
- Suspected of causing genetic defects.
- Harmful to aquatic life with long lasting effects.

Precautionary statements:

- Do not handle until all safety precautions have been read and understood.
- Avoid breathing mist/vapors/spray.
- 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.
- Immediately call a POISON CENTER/doctor.
- Take off contaminated clothing and wash it before reuse.

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

Relevant ingredients:

| CAS No. | Designation | Concentration | Classification |
|------------------|---|---------------|--|
| CAS 2425-79-8 | 1,4-Bis(2,3-epoxypropoxy)butane | 25 - 50 % | Acute Toxicity - oral - Category 4. Acute Toxicity - dermal - Category 4. Acute Toxicity - inhalative - Category 4. Skin Irritation - Category 2. Eye Damage - Category 1. Sensitization - skin - Category 1. Aquatic toxicity - chronic - Category 3. |
| CAS 13236-02-7 | 1,2,3-tris(2,3-Epoxypropoxy)propane | 10 - 25 % | Acute Toxicity - oral - Category 4. Eye Damage - Category 1. Germ cell mutagenicity - Category 2. Aquatic toxicity - chronic - Category 3. |
| CAS 1384855-91-7 | Esterification products of acrylic acid and 2,2,2',2'-tetrakis(hydroxymethyl)-3,3'-oxydipropan-1-ol | 10 - 25 % | Eye Irritation - Category 2A. Sensitization - skin - Category 1. Aquatic toxicity - chronic - Category 3. |
| CAS 13048-34-5 | 1,10-Decanediyl diacrylate | 2.5 - 10 % | Skin Irritation - Category 2. Eye Irritation - Category 2A. |

4. First aid measures

| | |
|-------------------------|---|
| General information: | First aider: Pay attention to self-protection! If medical advice is needed, have product container or label at hand. Take off 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 problems persist. |
| 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. Seek the attention of an ophthalmologist immediately. |
| 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. Keep airway open. Seek medical attention. |

Most important symptoms/effects, acute and delayed

Causes serious eye damage. Causes skin irritation. May cause an allergic skin reaction. Harmful if swallowed.

Information to physician

Treat symptomatically.

5. Fire fighting measures

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|--|--|
| 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: Carbon black, Carbon monoxide and carbon dioxide

| | |
|--|--|
| Protective equipment and precautions for firefighters: | Wear a self-contained breathing apparatus and chemical protective clothing. |
| Additional information: | Heating will lead to pressure increase: Danger of bursting and explosion. Keep containers cool with water spray. 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: | Avoid exposure. Provide adequate ventilation. If possible, eliminate leakage. Do not breathe mist/vapors/spray. Avoid contact with the substance. Wear appropriate protective equipment. Take off contaminated clothing and wash it before reuse. Keep unprotected people away. |
|-----------------------|---|

Environmental precautions:

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

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). 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 contaminated clothing and wash it before reuse.

Have eye wash bottle or eye rinse ready at work place.

Precautions against fire and explosion:

Keep away from heat.

When handling larger quantities, take precautionary measures against electrostatic charging.

Keep away from sources of ignition - No smoking.

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

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.

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

Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Respiratory protection: 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.
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. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Take off contaminated clothing and wash it before reuse. Have eye wash bottle or eye rinse ready at work place.

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

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|--|--|
| Appearance: | Physical state at 68 °F and 101.3 kPa: liquid Form: viscous |
| Odor: | No data available |
| Odor threshold: | No data available |
| pH: | neutral |
| 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: | >= 1 g/mL |
| Water solubility: | insoluble |
| Partition coefficient: n-octanol/water: | No data available |
| 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 hazardous reaction when handled and stored according to provisions.

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 hazardous decomposition products when regulations for storage and handling are observed.

Thermal decomposition: No data available

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): Acute Toxicity - oral - Category 4 = Harmful if swallowed.

Acute toxicity (dermal): Lack of data.

Acute toxicity (inhalative): Lack of data.

Skin corrosion/irritation: Skin Irritation - Category 2 = Causes skin irritation.

Serious eye damage/irritation: Eye Damage - Category 1 = Causes serious eye damage.

Sensitisation to the respiratory tract: Lack of data.

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

Germ cell mutagenicity/Genotoxicity: Germ cell mutagenicity -
Category 2 = Suspected of causing genetic defects.

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): Lack of data.

Aspiration hazard: Lack of data.

Other information: Information about 1,4-Bis(2,3-epoxypropoxy)butane:

LD50 Rat, oral: 1,163 mg/kg/bw (OECD 401)

LD50 Rat, dermal: > 2,150 mg/kg/bw (OECD 402)

Information about 1,2,3-tris(2,3-Epoxypropoxy)propane:

LD50 Rat, oral: 300 - 2,000 mg/kg/bw (OECD 423)

LD50 Rat, dermal: > 2,000 mg/kg (OECD 402)

Information about Esterification products of acrylic acid and

2,2,2',2'-tetrakis(hydroxymethyl)-3,3'-oxydipropan-1-ol:

LD50 Rat, oral: > 2,000 mg/kg (OECD 423)

LD50 Rabbit, dermal: > 2,000 mg/kg (read across)

Symptoms

In case of ingestion:

Irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract.

After contact with skin: Irritation, redness

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 1,4-Bis(2,3-epoxypropoxy)butane:
 Fish toxicity:
 EC50 Danio rerio (zebrafish): 24 mg/L/96h (OECD 203)
 Daphnia toxicity:
 EC50 Daphnia magna (Big water flea): 76 mg/L/24h (OECD 202)
 Algae toxicity:
 EL50 Pseudokirchneriella subcapitata (green algae), growth rate: > 160 mg/L/72h (OECD 201)
 NOELR Pseudokirchneriella subcapitata (green algae), growth rate: 40 mg/L/72h (OECD 201)

Mobility in soil

No data available

Persistence and degradability

Further details: No data available

Additional ecological information

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

13. Disposal considerations

Product

Recommendation: Do not dispose of with household waste.
 Special waste. Incinerate according to applicable local, state and federal regulations.

Package

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

14. Transport information

UN number

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

UN proper shipping name

ADR/RID, IMDG, IATA-DGR:
 Not restricted

Transport hazard class(es)

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

Packing group

ADR/RID, IMDG, IATA-DGR:

not applicable

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)

Proper shipping name:

Not restricted

Sea transport (IMDG)

Proper shipping name::

Not restricted

Marine pollutant:

no

Air transport (IATA)

Proper shipping name::

Not restricted

Further information

No dangerous good in sense of these transport regulations.

15. Regulatory information

National regulations - U.S. Federal Regulations

1,4-Bis(2,3-epoxypropoxy)butane:

TSCA Inventory: listed

1,2,3-tris(2,3-Epoxypropoxy)propane:

TSCA Inventory: listed

Esterification products of acrylic acid and

TSCA Inventory: listed; UVCB

2,2,2',2'-tetrakis(hydroxymethyl)-3,3'-oxydipropyl-1-ol:

1,10-Decanediyl diacrylate:

TSCA Inventory: listed

National regulations - U.S. State Regulations

No data available

16. Other information

Text for labeling:

Contains 25 - 50 % 1,4-Bis(2,3-epoxypropoxy)butane, 10 - 25 %

1,2,3-tris(2,3-Epoxypropoxy)propane, 10 - 25 % Esterification products of acrylic acid and 2,2,2',2'-tetrakis(hydroxymethyl)-3,3'-oxydipropyl-1-ol, 2.5 - 10 % 1,10-Decanediyl diacrylate.

Hazard rating systems:



NFPA Hazard Rating:

Health: 3 (Serious)

Fire: 2 (Moderate)

Reactivity: 0 (Minimal)

HMIS Version III Rating:

Health: 3 (Serious) - Chronic effects

Flammability: 2 (Moderate)

Physical Hazard: 0 (Minimal)

Personal Protection: X = Consult your supervisor

| | | |
|-----------------|---|---|
| HEALTH | * | 3 |
| FLAMMABILITY | | 2 |
| 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
 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
 DMEL: Derived minimal effect level
 DNEL: Derived no-effect level
 EC: European Community
 EC50: Effective Concentration 50%
 EL50: Effective loading rate 50%
 EmS: Emergency Response Procedures for Ships Carrying Dangerous Goods
 EN: European Standard
 EQ: Excepted quantities
 Eye Damage: Eye damage
 Eye Irritation: Eye irritation
 Germ cell mutagenicity: Mutagenicity
 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
 LD50: Lethal dose 50%
 MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
 MFSU: Manufacture, formulation, supply and use
 OECD: Organisation for Economic Co-operation and Development
 OSHA: Occupational Safety and Health Administration
 PBT: Persistent, bioaccumulative and toxic
 PNEC: Predicted no-effect concentration
 RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
 Sensitization - skin: Skin sensitisation
 Skin Irritation: Skin irritation
 TRGS: Technical Rules for Hazardous Substances
 vPvB: Very persistent and very bioaccumulative

Reason of change:

Changes in section 2: Classification, labeling
 Changes in section 3: Composition/information on ingredients
 General revision

Date of first version:

2/15/2022

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.