

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: 617HG5 - OrthoEpoX GreenLine

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

General use: For orthopaedic procedures, for producing molds.

1.3 Details of the supplier of the safety data sheet

Company name: Otto Bock HealthCare plc
Street/POB-No.: 32, Parsonage Road
Postal Code, city: TW20 OLD Englefield Green, Egham
Surrey
Great Britain

WWW: www.ottobock.co.uk
E-mail: bockuk@ottobock.com
Telephone: 01784 744 900
Telefax: 01784 744 901

Department responsible for information:
Russell Pizzey, Telephone: 01784 744 900

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

1.4 Emergency telephone number

GIZ-Nord, Germany, Telephone: +49 (0)551-19240

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to EC regulation 1272/2008 (CLP)

Acute Tox. 4; H302 Harmful if swallowed.
Skin Irrit. 2; H315 Causes skin irritation.
Eye Dam. 1; H318 Causes serious eye damage.
Skin Sens. 1; H317 May cause an allergic skin reaction.
Aquatic Chronic 3; H412 Harmful to aquatic life with long lasting effects.

2.2 Label elements

Labelling (CLP)



Signal word: **Danger**

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Hazard statements:

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H412	Harmful to aquatic life with long lasting effects.

Precautionary statements:

P261	Avoid breathing mist/vapours/spray.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection.
P302+P352	IF ON SKIN: Wash with plenty of water/soap.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor.
P362+P364	Take off contaminated clothing and wash it before reuse.

Special labelling

Text for labelling: Contains:
 1,4-bis(2,3-Epoxypropoxy)butane
 1,2,3-tris(2,3-Epoxypropoxy)propane
 Esterification products of acrylic acid and
 2,2,2',2'-tetrakis(hydroxymethyl)-3,3'-oxydipropan-1-ol

2.3 Other hazards

Special danger of slipping by leaking/spilling product.

Results of PBT and vPvB assessment:

No data available

SECTION 3: Composition/information on ingredients

3.1 Substances: not applicable

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3.2 Mixtures

Hazardous ingredients:

Ingredient	Designation	Content	Classification
REACH 01-2119494060-45-xxxx EC No. 219-371-7 CAS 2425-79-8	1,4-bis(2,3-Epoxypropoxy)butane	25 - 50 %	Acute Tox. 4; H302. Acute Tox. 4; H312. Acute Tox. 4; H332. Skin Irrit. 2; H315. Eye Irrit. 2; H319. Skin Sens. 1; H317. Aquatic Chronic 3; H412.
REACH 01-2120804934-53-xxxx EC No. 236-211-1 CAS 13236-02-7	1,2,3-tris(2,3-Epoxypropoxy)propane	10 - 25 %	Acute Tox. 4; H302. Eye Dam. 1; H318.
list no. 800-838-4 CAS 1384855-91-7	Esterification products of acrylic acid and 2,2,2',2'-tetrakis(hydroxymethyl)-3,3'-oxydipropan-1-ol	10 - 25 %	Eye Irrit. 2; H319. Skin Sens. 1; H317. Aquatic Chronic 3; H412.
EC No. 235-922-4 CAS 13048-34-5	1,10-Decanediyldiacrylate	2.5 - 10 %	Skin Irrit. 2; H315. Eye Irrit. 2; H319.

Full text of H- and EUH-statements: see section 16.

SECTION 4: First aid measures
4.1 Description of 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.

4.2 Most important symptoms and effects, both acute and delayed

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

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Water spray jet, foam, extinguishing powder, carbon dioxide

Extinguishing media which must not be used for safety reasons:

Full water jet

5.2 Special hazards arising from the substance or mixture

May form dangerous gases and vapours in case of fire.

Furthermore, there may develop: Carbon black, Carbon monoxide and carbon dioxide

5.3 Advice for firefighters

Special protective equipment for firefighters:

Wear a self-contained breathing apparatus and chemical protective clothing.

Additional information:

Hazchem-Code: -

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. If possible, eliminate leakage.

Do not breathe mist/vapours/spray. Avoid contact with the substance.

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

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning 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.

6.4 Reference to other sections

Refer additionally to section 8 and 13.

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SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed. Do not breathe mist/vapours/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.

7.2 Conditions for safe storage, including any incompatibilities

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

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters**

Additional information: Contains no substances with occupational exposure limit values.

DNEL/DMEL:

Information about 1,4-bis(2,3-Epoxypropoxy)butane:
DNEL workers, inhalative, systemic, long-term: 4.7 mg/m³
DNEL workers, dermal, systemic, long-term: 6.66 mg/kg bw/d
DNEL consumers, inhalative, systemic, long-term: 1.16 mg/m³
DNEL consumers, dermal, systemic, long-term: 3.33 mg/kg bw/d
DNEL consumers, oral, systemic, long-term: 0.33 mg/kg bw/d

PNEC:

Information about 1,4-bis(2,3-Epoxypropoxy)butane:
PNEC water (freshwater): 0.024 mg/L
PNEC water (marine water): 0.002 mg/L
PNEC sewage treatment plant: 100 mg/L
PNEC sediment (freshwater): 0.084 mg/kg dw/d
PNEC sediment (marine water): 0.008 mg/kg dw/d
PNEC soil: 0.003 mg/kg dw/d
PNEC oral (Secondary Poisoning): 0.028 mg/kg food

8.2 Exposure controls

Provide for good ventilation or exhaust system or work with completely self-contained equipment.

Personal protection equipment

Occupational exposure controls

- Respiratory protection: In case of inadequate ventilation wear respiratory protection. The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. Recommendation: Use filter type A (= against vapours of organic substances) according to EN 14387.
- Hand protection: Protective gloves according to EN 374. Observe glove manufacturer's instructions concerning penetrability and breakthrough time.
- Eye protection: Tightly sealed goggles according to EN 166.
- Body protection: Wear suitable protective clothing.
- General protection and hygiene measures: Do not breathe mist/vapours/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.

People who suffer from skins problems, asthma, allergies, chronic or recurring respiratory illnesses must not be deployed in processes, which use this mixture.

Environmental exposure controls

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

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance:	Physical state at 20 °C and 101.3 kPa: liquid Form: viscous
Odour:	No data available
Odour 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
Vapour pressure:	No data available
Vapour 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
Decomposition temperature:	No data available
Viscosity, kinematic:	No data available
Explosive properties:	No data available
Oxidizing characteristics:	No data available

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9.2 Other information

Additional information: No data available

SECTION 10: Stability and reactivity**10.1 Reactivity**

Refer to subsection "Possibility of hazardous reactions".

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

10.4 Conditions to avoidKeep away from heat sources, sparks and open flames.
Protect from direct sunlight.**10.5 Incompatible materials**

No data available

10.6 Hazardous decomposition products

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

Thermal decomposition: No data available

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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 Tox. 4; H302 = Harmful if swallowed.</p> <p>Acute toxicity (dermal): Lack of data.</p> <p>Acute toxicity (inhalative): Lack of data.</p> <p>Skin corrosion/irritation: Skin Irrit. 2; H315 = Causes skin irritation.</p> <p>Serious eye damage/irritation: Eye Dam. 1; H318 = Causes serious eye damage.</p> <p>Sensitisation to the respiratory tract: Lack of data.</p> <p>Skin sensitisation: Skin Sens. 1; H317 = 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: Lack of data.</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): Lack of data.</p> <p>Aspiration hazard: Lack of data.</p>
Other information:	<p>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)</p> <p>Information about 1,2,3-tris(2,3-Epoxypropoxy)propane: LD50 Rat, oral: 300 - 2,000 mg/kg/bw (OECD 423)</p>

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.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:	<p>Harmful to aquatic life with long lasting effects.</p> <p>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)</p>
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12.2 Persistence and degradability

Further details: No data available

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water:

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

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

SECTION 13: Disposal considerations**13.1 Waste treatment methods****Product**

Waste key number: 07 02 08* = other still bottoms and reaction residues
MFSU = manufacture, formulation, supply and use
* = Evidence for disposal must be provided.

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.

SECTION 14: Transport information**14.1 UN number**

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

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

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

14.4 Packing group

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

14.5 Environmental hazards

Marine pollutant: no

14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

No data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations - Great Britain

Hazchem-Code: -
No data available

National regulations - EC member states

Labelling of packaging with <= 125mL content



Signal word: **Danger**

Hazard statements: H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements: P261 Avoid breathing mist/vapours/spray.
P280 Wear protective gloves/protective clothing/eye protection.
P302+P352 IF ON SKIN: Wash with plenty of water/soap.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER/doctor.
P362+P364 Take off contaminated clothing and wash it before reuse.

Further regulations, limitations and legal requirements:
Use restriction according to REACH annex XVII, no.: 3, 75

15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment is not required.

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SECTION 16: Other information**Further information**

Wording of the H-phrases under paragraph 2 and 3:

- H302 = Harmful if swallowed.
- H312 = Harmful in contact with skin.
- H315 = Causes skin irritation.
- H317 = May cause an allergic skin reaction.
- H318 = Causes serious eye damage.
- H319 = Causes serious eye irritation.
- H332 = Harmful if inhaled.
- H412 = Harmful to aquatic life with long lasting effects.

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
- 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
- EC50: Effective Concentration 50%
- EC: European Community
- EL50: Effective loading rate 50%
- EN: European Standard
- EU: European Union
- MFSU: Manufacture, formulation, supply and use
- IATA: International Air Transport Association
- IBC Code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
- IMDG Code: International Maritime Dangerous Goods Code
- LD50: Lethal dose 50%
- MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
- OECD: Organisation for Economic Co-operation and Development
- OSHA: Occupational Safety and Health Administration
- PBT: Persistent, bioaccumulative and toxic
- PNEC: Predicted no-effect concentration
- REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
- RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
- vPvB: Very persistent and very bioaccumulative

Date of first version: 15/2/2022

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.