

1. Product and company identification

Product identifier

Trade name: 616B60 - Resin Film

This safety data sheet pertains to the following products:

616B60=2 = Harzfolie

616B60=5 = Harzfolie

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

General use: Epoxy resin (film), for orthopedic procedures.
Reserved for industrial and professional use.

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: solid

Form: viscous liquid

Odor: No data available

Classification: Skin Irritation - Category 2. Eye Irritation - Category 2A. Sensitization - skin - Category 1. Aquatic toxicity - chronic - Category 2.

Hazard symbols:



Signal word: **Warning**

Hazard statements:

- Causes skin irritation.
- May cause an allergic skin reaction.
- Causes serious eye irritation.
- Toxic to aquatic life with long lasting effects.

Precautionary statements:

- Avoid breathing vapors.
- Avoid release to the environment.
- Wear protective gloves/protective clothing/eye protection.
- IF ON SKIN: Wash with plenty of water/soap.
- 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.
- 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

see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: Film: polymer (modified), paper (modified), epoxy resin

Information about epoxy resin:

Relevant ingredients:

| CAS No. | Designation | Concentration | Classification |
|----------------|--|---------------|---|
| CAS 25068-38-6 | Bisphenol A epoxy resin (molecular-weight < 700) | 80 - 95 % | Skin Irritation - Category 2. Eye Irritation - Category 2A. Sensitization - skin - Category 1. Aquatic toxicity - chronic - Category 2. |
| CAS 9003-36-5 | Bisphenol-F-epichlorhydrine resin | 5 - 15 % | Skin Irritation - Category 2. Eye Irritation - Category 2A. Sensitization - skin - Category 1. Aquatic toxicity - chronic - Category 2. |

4. First aid measures

In case of inhalation: Move victim to fresh air; if necessary, provide artificial respiration or oxygen. If unconscious place in recovery position and seek medical advice.

Following skin contact: After contact with skin, wash immediately with soap and plenty of water. Take off contaminated clothing and wash it before reuse. 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 consult an ophthalmologist.

After swallowing: Do not induce vomiting without medical assistance.
Rinse mouth immediately and drink plenty of water.
Never give anything by mouth to an unconscious person.
In case of vomiting, lay at least head on side. Immediately get medical attention.

Most important symptoms/effects, acute and delayed

May cause an allergic skin reaction. Causes serious eye irritation. Causes skin irritation.
After ingestion: stomachache, Nausea
In case of inhalation: irritation to respiratory tract

Information to physician

Treat symptomatically.

5. Fire fighting measures

Flash point/flash point range:

302 °F

(Reaction product: Bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight ≤ 700))

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: hydrogen cyanide, isocyanates, Ammonia, amines, nitrogen oxides (NOx), carbon monoxide and carbon dioxide

Protective equipment and precautions for firefighters:

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

Additional information:

Use fine water spray to cool endangered containers. 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:

Eliminate all ignition sources if safe to do so. Provide adequate ventilation.
Wear appropriate protective equipment. Take off contaminated clothing and wash it before reuse. Keep unprotected people away.
Avoid breathing vapors. Avoid contact with skin and eyes.

Environmental precautions:

Do not allow to enter into ground-water, surface water or drains.
In case of release, notify competent authorities.

Methods for clean-up:

Soak up with absorbent materials such as sand, siliceus earth, acid- or universal binder.
Store in special closed containers and dispose of according to ordinance. Final cleaning.

7. Handling and storage

Handling

Advices on safe handling: Provide adequate ventilation.

Wear appropriate protective equipment. Take off contaminated clothing and wash it before reuse.

Avoid breathing vapors. Avoid contact with skin and eyes.

Do not eat, drink or smoke when using this product. Wash hands before breaks and after work.

Eye wash facility must be provided.

Storage

Requirements for storerooms and containers:

Keep container tightly closed in a cool, well-ventilated place. Only use containers specifically approved for the substance/product. Protect from heat and direct sunlight.

Hints on joint storage:

Keep away from food, drink and animal feedingstuffs.

8. Exposure controls / personal protection

Engineering controls

Provide good ventilation and/or an exhaust system in the work area.

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: nitrile rubber, PVC, neoprene

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

Respiratory protection: When vapors form, use 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.

Use respiratory protection whenever ventilation is inadequate.

General hygiene considerations:

Avoid breathing vapors. Avoid contact with skin and eyes.

Do not eat, drink or smoke when using this product.

Take off contaminated clothing and wash it before reuse.

Wash hands before breaks and after work. Eye wash facility must be provided.

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: solid

Form: viscous liquid

| | |
|--|---|
| Odor: | No data available |
| Odor threshold: | No data available |
| pH: | not applicable |
| Melting point/freezing point: | No data available |
| Initial boiling point and boiling range: | not applicable |
| Flash point/flash point range: | 302 °F (Reaction product: Bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight \leq 700)) |
| Evaporation rate: | No data available |
| Flammability: | not applicable |
| Explosion limits: | LEL (Lower Explosion Limit): not applicable UEL (Upper Explosive Limit): not applicable |
| Vapor pressure: | not applicable |
| Vapor density: | not applicable |
| Density: | 1.2 g/cm ³ |
| Water solubility: | partially soluble |
| Partition coefficient: n-octanol/water: | $\geq 2.918 \log K(o/w)$ (Reaction product: Bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight \leq 700), OECD 117) Based on the n-octanol/water partition coefficient accumulation in organisms is possible. |
| Auto-ignition temperature: | No data available |
| Thermal decomposition: | No data available |
| Viscosity, dynamic: | at 140 °F: $\geq 200,000$ mPa*s |
| Explosive properties: | not applicable |
| Oxidizing characteristics: | not applicable |

10. Stability and reactivity

| | |
|-------------------------------------|---|
| Reactivity: | no data available |
| Chemical stability: | Stable under recommended storage conditions. |
| Possibility of hazardous reactions: | Excessive heating: exothermic reactions |
| Conditions to avoid: | Protect from heat and direct sunlight. |
| Incompatible materials: | No data available |
| Hazardous decomposition products: | hydrogen cyanide, isocyanates, Ammonia, amines, nitrogen oxides (NOx), carbon monoxide and carbon dioxide |
| 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): Lack of data.

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 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): Lack of data.

Aspiration hazard: Lack of data.

Other information: Information about Reaction product: Bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight ≤ 700):

LD50, Rat, oral: > 2,000 mg/kg

LD50, Rat, dermal: > 2,000 mg/kg

Information about Bisphenol-F-epichlorhydrine resin:

LD50, Rat, oral: > 5,000 mg/kg

Symptoms

In case of inhalation: irritation to respiratory tract

In case of ingestion: stomachache, Nausea

12. Ecological information

Ecotoxicity

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

Information about Reaction product: Bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight ≤ 700):

Algae toxicity:

EC50 *Scenedesmus capricornutum*: 9.4 mg/L/72h

Daphnia toxicity:

EC50 *Daphnia magna* (Big water flea): 1.1 - 3.8 mg/L/48h (OECD 202).

NOEC *Daphnia magna* (Big water flea): 0.3 mg/L/21d (OECD 211).

Fish toxicity:

LC50 *Oncorhynchus mykiss*: 1.2 mg/L/96h

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: Dispose of waste according to applicable legislation.

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:

UN 3077

UN proper shipping name

ADR/RID, IMDG, IATA-DGR:

UN 3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

(Reaction product: Bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight ≤ 700), Bisphenol F Epoxy Resin)

Transport hazard class(es)

ADR/RID: Class 9, Code: M7

IMDG: Class 9, Subrisk -

IATA-DGR: Class 9

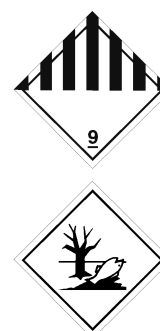
Packing group

ADR/RID, IMDG, IATA-DGR:

III

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: UN3077
 Proper shipping name: UN 3077,
 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
 N.O.S.
 (Reaction product: Bisphenol-A-(epichlorhydrin) epoxy resin
 (number average molecular weight \leq 700), Bisphenol F Epoxy
 Resin)
 Hazard class or Division: 9
 Packing Group: III
 Labels: 9
 Symbols: G
 Special Provisions: 8, 146, 335, 384, 441, A112, B54, B120, IB8, IP3, N20, N91,
 T1, TP33
 Packaging – Exceptions: 155
 Packaging – Non-bulk: 213
 Packaging – Bulk: 240
 Quantity limitations – Passenger aircraft / rail: No limit
 Quantity limitations – Cargo only: No limit
 Vessel stowage – Location: A



Sea transport (IMDG)

UN number: UN 3077
 Proper shipping name: UN 3077,
 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
 (Reaction product: Bisphenol-A-(epichlorhydrin) epoxy resin (number
 average molecular weight \leq 700), Bisphenol F Epoxy Resin)
 Class or division, Subsidiary risk: Class 9, Subrisk -
 Packing Group: III
 EmS: F-A, S-F
 Special Provisions: 274 335 375 966 967 969
 Limited quantities: 5 kg
 Excepted quantities: E1
 Package - Instructions: P002, LP02
 Package - Provisions: PP12
 IBC - Instructions: IBC08
 IBC - Provisions: B3
 Tank instructions - IMO: -
 Tank instructions - UN: T1, BK2, BK2, BK3
 Tank instructions - Provisions: TP33
 Stowage and handling: Category A. SW23
 Properties and observations: -
 Marine pollutant: yes
 Segregation group: none

Air transport (IATA)

| | |
|---|---|
| UN/ID number: | UN 3077 |
| Proper shipping name:: | UN 3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Reaction product: Bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight ≤ 700), Bisphenol F Epoxy Resin) |
| Class or division, Subsidiary risk: | Class 9 |
| Packing Group: | III |
| Hazard label: | Miscellaneous & Environmentally hazardous |
| Excepted Quantity Code: | E1 |
| Passenger and Cargo Aircraft: Ltd.Qty.: | Pack.Instr. Y956 - Max. Net Qty/Pkg. 30 kg G |
| Passenger and Cargo Aircraft: | Pack.Instr. 956 - Max. Net Qty/Pkg. 400 kg |
| Cargo Aircraft only: | Pack.Instr. 956 - Max. Net Qty/Pkg. 400 kg |
| Special Provisions: | A97 A158 A179 A197 A215 |
| Emergency Response Guide-Code (ERG): | 9L |

15. Regulatory information

National regulations - U.S. Federal Regulations

Bisphenol A epoxy resin (molecular-weight < 700): TSCA Inventory: listed

Bisphenol-F-epichlorhydrine resin: TSCA Inventory: listed

National regulations - U.S. State Regulations

No data available

National regulations - Canada

Bisphenol A epoxy resin (molecular-weight < 700): DSL: listed

Bisphenol-F-epichlorhydrine resin: DSL: listed

National regulations - Great Britain

Hazchem-Code: 2Z

16. Other information

Text for labeling: Contains 80 - 95 % Bisphenol A epoxy resin (molecular-weight < 700), 5 - 15 % Bisphenol-F-epichlorhydrine resin.
Contains Reaction product: Bisphenol-A-(epichlorhydrin) epoxy resin (number average molecular weight ≤ 700) and Bisphenol-F-epichlorhydrine resin.

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 - 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%
 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
 NOEC: No Observed Effect Concentration
 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
 Sensitization - skin: Skin sensitisation
 Skin Irritation: Skin irritation
 TRGS: Technical Rules for Hazardous Substances
 UN: United Nations
 vPvB: Very persistent and very bioaccumulative

Reason of change: Changes in section 14: IMDG 2025

Date of first version: 8/18/2017

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.