

## 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

### Recommended use and restrictions on use

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

### Initial supplier identifier

Company name: Otto Bock HealthCare Canada Ltd.

Street/POB-No.: 5470 Harvester Road

Postal Code, city: Burlington, ON L7L 5N5, CA  
Canada

WWW: www.ottobock.ca

E-mail: info.canada@ottobock.com

Telephone: (800) 665-3327

Telefax: (800) 463-3659

Department responsible for information:

Mark Agro, Telephone: (800) 665-3327 (9 am - 5 pm)

Additional information:

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

### Emergency phone number

**COLLECT, Telephone: (613) 996-6666**

**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 20 °C and 101.3 kPa: solid

Form: viscous liquid

Odor: No data available

Classification: Skin Irritation 2. Eye Irritation 2A. Sensitization - skin 1. Aquatic toxicity - chronic 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) and WHMIS in Canada.

## Hazards not otherwise classified

see section 11: Toxicological information

## 3. Composition / Information on ingredients

Chemical characterisation: 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 2. Eye Irritation 2A. Sensitization - skin 1. Aquatic toxicity - chronic 2.
CAS 9003-36-5	Bisphenol-F-epichlorhydrine resin	5 - 15 %	Skin Irritation 2. Eye Irritation 2A. Sensitization - skin 1. Aquatic toxicity - chronic 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 and effects, both 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:

150 °C

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

Auto-ignition temperature: No data available

Suitable extinguishing media:

water spray jet, foam, extinguishing 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

Special protective equipment and precautions for fire-fighters:

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, siliceous 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/vapour/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 20 °C 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:	150 °C (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 <sup>3</sup>
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 60 °C: $\geq 200,000$ 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 (NO <sub>x</sub> ), 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 2 = Causes skin irritation.

Serious eye damage/irritation: Eye Irritation 2A = Causes serious eye irritation.

Sensitisation to the respiratory tract: Lack of data.

Skin sensitisation: Sensitization - skin 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  $\leq 700$ ):

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  $\leq 700$ ):

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  $\leq 700$ ), 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:

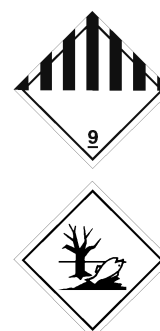
III

## 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



### Canada: Transportation of Dangerous Goods (TDG)

UN Number:	UN3077
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)
TDG class:	9
Packing group:	III
Special provisions:	16, 99
Explosive limit and limited quantity index:	5 kg
Marine pollutant:	P



### 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  $\leq$  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 - Canada

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

Bisphenol-F-epichlorhydrine resin: DSL: listed

### 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

## 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  $\leq$  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  
WHMIS: Workplace Hazardous Materials Information System

Reason of change: Changes in section 14: IMDG 2025

Date of first version: 18/8/2017

### 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.