

## 1. Identification

### Product identifier

Trade name: 616B60 - Resin Film

### 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  
Zip code, city: Salt Lake City, UT 84120  
USA

WWW: [www.ottobockus.com](http://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](mailto:USRegulatory@ottobock.com)

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

### Emergency telephone 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. Hazard identification

### Classification of the substance or mixture

Skin Irritation - Category 2	Causes skin irritation.
Eye Irritation - Category 2A	Causes serious eye irritation.
Sensitization - skin - Category 1	May cause an allergic skin reaction.
Aquatic toxicity - chronic - Category 2	Toxic to aquatic life with long lasting effects.

### Label elements

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.

### 3. Composition/information on ingredients

#### Mixtures

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

Information about epoxy resin:

Relevant ingredients:

CAS No.	Designation	Concentration	Classification
CAS 25068-38-6	Reaction product: Bisphenol-A-(epichlorohydrin) epoxy resin (number average molecular weight $\leq$ 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-epichlorohydrin resin	5 - 15 %	Skin Irritation - Category 2. Eye Irritation - Category 2A. Sensitization - skin - Category 1. Aquatic toxicity - chronic - Category 2.

The actual concentration or concentration range is withheld as a trade secret.

### 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

### Suitable (and unsuitable) extinguishing media

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, protective equipment and emergency procedures

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 and material for containment and cleaning up

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

### Precautions for safe 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.

### Conditions for safe storage, including any incompatibilities

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

### Appropriate engineering controls

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

### Personal protection equipment (PPE)

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.  
Hand protection: 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.  
Eye protection: Tightly sealed goggles according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2010.  
Body protection: Wear suitable protective clothing.  
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

Physical state at 68 °F and 101.3 kPa	solid
Color:	Form: viscous liquid colorless
Odor:	No data available
Odor threshold:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	not applicable
Flammability:	not applicable
Explosion limits:	LEL (Lower Explosion Limit): not applicable UEL (Upper Explosive Limit): not applicable
Flash point/flash point range:	302 °F (Reaction product: Bisphenol-A-(epichlorohydrin) epoxy resin (number average molecular weight $\leq 700$ ))
Evaporation rate:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
pH:	not applicable
Dynamic viscosity:	at 140 °F: $\geq 200,000$ mPa*s
Water solubility:	partially soluble
Partition coefficient: n-octanol/water:	$\geq 2.918 \log K(o/w)$ (Reaction product: Bisphenol-A-(epichlorohydrin) epoxy resin (number average molecular weight $\leq 700$ ), OECD 117) Based on the n-octanol/water partition coefficient accumulation in organisms is possible.
Vapor pressure:	not applicable
Density:	1.2 g/cm <sup>3</sup>
Vapor density:	not applicable
Particle characteristics:	No data available

### Additional information

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

## 11. Toxicological information

### Information on toxicological effects

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-(epichlorohydrin) 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-epichlorohydrin 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-(epichlorohydrin) 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

### Persistence and degradability

Further details: No data available

### Bioaccumulative potential

Partition coefficient: n-octanol/water:

$\geq 2.918 \log K(o/w)$  (Reaction product: Bisphenol-A-(epichlorohydrin) epoxy resin

(number average molecular weight  $\leq 700$ ), OECD 117)

Based on the n-octanol/water partition coefficient accumulation in organisms is possible.

### Mobility in soil

No data available

### Other adverse effects

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

## 13. Disposal considerations

### Waste treatment methods

#### 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

DOT: UN3077

IMDG, IATA-DGR: UN 3077

### UN proper shipping name

DOT, IMDG, IATA-DGR: UN 3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Reaction product: Bisphenol-A-(epichlorohydrin) epoxy resin (number average molecular weight  $\leq 700$ ), Bisphenol F Epoxy Resin)

### Transport hazard class(es)

DOT: 9

IMDG: Class 9, Subrisk -

IATA-DGR: Class 9



### Packing group

DOT, IMDG, IATA-DGR: III

### Environmental hazards

Marine pollutant: yes

### Transport in bulk according to IMO instruments

No data available

### Special precautions for user

#### USA: Department of Transportation (DOT)

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)

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)

Proper shipping name:	UN 3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Reaction product: Bisphenol-A-(epichlorohydrin) epoxy resin (number average molecular weight $\leq$ 700), Bisphenol F Epoxy Resin)
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

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

TSCA Inventory: listed

Bisphenol-F-epichlorohydrin resin:

TSCA Inventory: listed



### National regulations - U.S. State Regulations

No data available

### Further regulations, limitations and legal requirements

No data available

## 16. Other information

Text for labeling: Contains 80 - 95 % Reaction product: Bisphenol-A-(epichlorohydrin) epoxy resin (number average molecular weight  $\leq 700$ ), 5 - 15 % Bisphenol-F-epichlorohydrin resin.  
Contains Reaction product: Bisphenol-A-(epichlorohydrin) epoxy resin (number average molecular weight  $\leq 700$ ) and Bisphenol-F-epichlorohydrin resin.

Revision date: 1/1/2026

Date of first version: 8/18/2017

Reason of change: Changes in section 14: IATA-DGR 2026

#### Abbreviations and acronyms:

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  
DOT: Department of Transportation's Safety Regulations (USA)  
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  
Sensitization - skin: Skin sensitisation  
Skin Irritation: Skin irritation  
TRGS: Technical Rules for Hazardous Substances  
UN: United Nations  
vPvB: Very persistent and very bioaccumulative

### 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.