

1 Identification

Product identifier

Trade name: 616B60 - Resin Film

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

Email: 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 telephone number

COLLECT, Telephone: (613) 996-6666

Transport:

CONSULTANK Lutz Harder GmbH (Contract QUALI003)

Telephone: +49 (0)178-4337434 (from USA: 01149 178 4337434)

2 Hazard identification

Classification

Skin Irritation 2

Causes skin irritation.

Eye Irritation 2A

Causes serious eye irritation.

Sensitization - skin 1

May cause an allergic skin reaction.

Aquatic toxicity - chronic 2

Toxic to aquatic life with long lasting effects.

Information 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 vapours.
- 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.

Other hazards known to the supplier with respect to the product

3 Composition/Information on ingredients

Mixture

Chemical name: Film: polymer (modified), paper (modified), epoxy resin
Information about epoxy resin:

Hazardous ingredients:

CAS No.	Designation	Content	Classification
CAS 25068-38-6	Reaction product: Bisphenol-A-(epichlorohydrin) epoxy resin (number average molecular weight ≤ 700)	80 - 95 %	Skin Irritation 2. Eye Irritation 2A. Sensitization - skin 1. Aquatic toxicity - chronic 2.
CAS 9003-36-5	Bisphenol-F-epichlorohydrin resin	5 - 15 %	Skin Irritation 2. Eye Irritation 2A. Sensitization - skin 1. Aquatic toxicity - chronic 2.

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

4 First-aid measures

Description of necessary 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.

In case of 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.

In case of 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.

In case of 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.

Most important symptoms and effects, whether acute or 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

Indication of immediate medical attention and special treatment needed, if necessary

Treat symptomatically.

5 Fire-fighting measures

Suitable and unsuitable extinguishing media

Suitable extinguishing media:

water spray jet, foam, extinguishing powder, Carbon dioxide

Unsuitable extinguishing media:

Full water jet

Specific hazards arising from the product

May form dangerous gases and vapours 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, 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 vapours. 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

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

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 vapours. 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

Control parameters

Appropriate engineering controls

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

Individual protection measures, such as personal protective equipment

Respiratory protection: When vapours 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.
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 vapours. 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 20 °C and 101.3 kPa	solid
Colour:	Form: viscous liquid colourless
Odour:	No data available
Odour threshold:	No data available
Melting point and freezing point:	No data available
Boiling point or initial boiling point and boiling range:	not applicable
Flammability:	not applicable
Lower and upper explosion limit or lower and upper flammability limit:	LEL (Lower Explosion Limit): not applicable UEL (Upper Explosive Limit): not applicable
Flash point/flash point range:	150 °C (Reaction product: Bisphenol-A-(epichlorohydrin) epoxy resin (number average molecular weight ≤ 700))
Evaporation rate:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
pH:	not applicable
Dynamic viscosity:	at 60 °C: ≥ 200,000 mPa*s
Water solubility:	partially soluble
Partition coefficient — n-octanol/water:	≥ 2.918 log K(o/w) (Reaction product: Bisphenol-A-(epichlorohydrin) epoxy resin (number average molecular weight ≤ 700), OECD 117) Based on the n-octanol/water partition coefficient accumulation in organisms is possible.
Vapour pressure:	not applicable
Density and/or relative density	1.2 g/cm ³
Vapour 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 (NOx), carbon monoxide and carbon dioxide

11 Toxicological information

Information on the likely routes of exposure

No data available

Health hazard information

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-(epichlorohydrin) 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-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 ≤ 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 ≤ 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

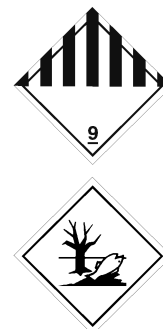
TDG: UN3077
IMDG, IATA-DGR: UN 3077

UN proper shipping name

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

Transport hazard class

TDG: 9
IMDG: Class 9, Subrisk -
IATA-DGR: Class 9



Packing group

TDG, IMDG, IATA-DGR: III

Environmental hazards

Marine pollutant: yes

Special precautions in connection with transport or conveyance either within or outside the premises

Canada: Transportation of Dangerous Goods (TDG)

Special Provisions: 16, 99

Explosive limit and limited quantity index: 5 kg

Marine pollutant: P

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 - Canada

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

Bisphenol-F-epichlorohydrin resin: DSL: listed

Further regulations, limitations and legal requirements

No data available

16 Other information

Text for labelling: 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: 18/8/2017

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
DSL: Domestic Substances List
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
TDG: Transportation of Dangerous Goods Regulation in Canada
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.