

SAFETY DATA SHEET

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

Revision date: 3/22/2018

Version: 11

Language: en-US

Date of print: 5/24/2018

ottobock. 616B - Collective Data Sheet for Prepreg materials

Material number 616B

Page: 1 of 8

1. Product and company identification

Product identifier

Trade name: 616B - Collective Data Sheet for Prepreg materials

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

General use: Fabric impregnated with bisphenol A epoxy resin (uncured) for orthopedic procedures.
Processing at Processing temperature 149 - 356 °F.
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

Dept. responsible for information:

Quality Department,
Telephone: +1 (801) 954-2304 (7 AM – 3 PM, Mountain Time),
Email: USRegulatory@ottobock.com

Additional information:

This safety data sheet pertains to the following products:
Otto Bock 616B10 - Epoxy Resin Prepreg with Woven Carbon Fabric
Otto Bock 616B11 - Epoxy Resin Prepreg with Woven Carbon Fabric, unidir.
Otto Bock 616B13 - Epoxy Resin Prepreg with Woven Aramid Fabric
Otto Bock 616B15 - Epoxy Resin Prepreg with Woven Dyneema Fabric

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

Emergency phone number

CHEMTREC, Telephone: +1 (800) 424-9300

2. Hazards identification

Emergency overview

Appearance: Form: Fabric: solid
matrix, (bisphenol epoxy resins, uncured): liquid
Color: milky, black or white

Odor: odorless

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

SAFETY DATA SHEET

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

Revision date: 3/22/2018

Version: 11

Language: en-US

Date of print: 5/24/2018

ottobock. 616B - Collective Data Sheet for Prepreg materials

Material number 616B

Page: 2 of 8

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:

Wear protective gloves/protective clothing/eye protection/face protection.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
Collect spillage.
Dispose of contents/container to hazardous or special waste collection point.

Regulatory status

This material is considered hazardous by the U.S. OSHA Hazard Communication Standard (29 CFR 1910.1200) and SIMDUT in Canada.

Hazards not otherwise classified

Processing by heating can produce vapours. For risks which have to be observed thereby, see section 7: Handling, section 8: Exposure controls / personal protection and section 11: Toxicology.
If handled and used properly, exposure to fibers is unlikely.
see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: fabric with matrix (bisphenol epoxy resins, uncured)

Relevant ingredients:

CAS No.	Designation	Content	Classification
CAS 25068-38-6	Bisphenol A epoxy resin (molecular-weight < 700)	10 - 25 %	Skin Irritation - Category 2. Eye Irritation - Category 2A. Sensitization - skin - Category 1. Aquatic toxicity - chronic - Category 2.
CAS 25036-25-3	Epichlorhydrin/ Bisphenol A Epoxy Resin	5 - 10 %	Skin Irritation - Category 2. Eye Irritation - Category 2A. Sensitization - skin - Category 1. Aquatic toxicity - chronic - Category 2.
CAS 28064-14-4	Bisphenol-F- epichlorhydrine resin	1 - 2.5 %	Skin Irritation - Category 2. Eye Irritation - Category 2A. Sensitization - skin - Category 1. Aquatic toxicity - chronic - Category 2.
CAS 67924-34-9	Bisphenol A - 4-tert-Butylphenol - Epichlorhydrin polymer	< 1 %	Skin Irritation - Category 2. Eye Irritation - Category 2A. Sensitization - skin - Category 1. Aquatic toxicity - chronic - Category 2.

SAFETY DATA SHEET

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

Revision date: 3/22/2018

Version: 11

Language: en-US

Date of print: 5/24/2018

ottobock. 616B - Collective Data Sheet for Prepreg materials

Material number 616B

Page: 3 of 8

4. First aid measures

In case of inhalation: Move victim to fresh air, put at rest and loosen restrictive clothing. Seek medical attention.

Following skin contact: Immediately remove all contaminated clothing. Wash with generous amount of water and soap. Seek medical attention if irritation persists.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Consult doctor afterwards.

Most important symptoms/effects, acute and delayed

Causes skin irritation.
May cause an allergic skin reaction.
Causes serious eye irritation.
Swallowing is not regarded as a possible way of exposition.

Information to physician

Treat symptomatically.

5. Fire fighting measures

Flash point/flash point range:

No data available

Auto-ignition temperature: No data available

Suitable extinguishing media:

Foam, dry chemical powder, water spray jet, Carbon dioxide.

Extinguishing media which must not be used for safety reasons:

strong water jet

Specific hazards arising from the chemical

Hazardous decomposition products: Toxic gases and vapors.
In case of fire may be liberated: Hydrochloric gas, carbon monoxide and carbon dioxide.

Protective equipment and precautions for firefighters:

Use a breathing apparatus independent of the ambient air (isolated apparatus) and a full protection outfit (suit) against chemicals.

Additional information:

Do not breathe fumes.
Cool endangered containers with water jetspray.
Do not allow water used to extinguish fire to enter drains, ground or waterways.
For that reason, provide adequate installations to retain fire water. Disposal of contaminated water and earth must take place according to local regulations.

6. Accidental release measures

Personal precautions:

Wear appropriate protective equipment.
Avoid contact with skin, eyes, and clothing.
Keep unprotected people away. Provide adequate ventilation.

Environmental precautions:

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

Methods for clean-up:

Take up mechanically, placing in appropriate containers for disposal. Final cleaning.

SAFETY DATA SHEET

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

Revision date: 3/22/2018

Version: 11

Language: en-US

Date of print: 5/24/2018

ottobock. 616B - Collective Data Sheet for Prepreg materials

Material number 616B

Page: 4 of 8

7. Handling and storage

Handling

Advices on safe handling: Wear appropriate protective equipment.
Avoid contact with skin, eyes, and clothing.
Provide good ventilation in the work area.

Precautions against fire and explosion:
Keep away from sources of ignition.

Storage

Requirements for storerooms and containers:
Keep container tightly closed and in a well-ventilated place. Keep container dry. storage temperature -0.4 °F. Avoid temperatures exceeding -0.4 °F.

Hints on joint storage: keep away from: strong oxidizing agents, strong alkalis, amines.
Keep away from food, drink and animal feedingstuffs.

8. Exposure controls / personal protection

Engineering controls

Requires good ventilation.
Processing (In case of warming): receptor hood for fumes/vapors
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: butyl caoutchouc (butyl rubber)-breakthrough time > 480 min
Processing (In case of warming):
Protective gloves against thermic risks.
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Respiratory protection: In case of insufficient ventilation, wear suitable respiratory equipment.
In case of warming: Use filter type A (= against vapors of organic substances) according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2.

General hygiene considerations:
Avoid contact with skin and eyes.
When using do not eat, drink or smoke.
Keep away from food, drink and animal feedingstuffs.
Wash hands before breaks and after work.
Change contaminated clothing.
In case of warming: Do not breathe vapors.
Have eye wash bottle or eye rinse ready at work place.

SAFETY DATA SHEET

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

Revision date: 3/22/2018

Version: 11

Language: en-US

Date of print: 5/24/2018

ottobock.

616B - Collective Data Sheet for Prepreg materials

Material number 616B

Page:

5 of 8

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:	Form: Fabric: solid matrix, (bisphenol epoxy resins, uncured): liquid Color: milky, black or white
Odor:	odorless
Odor threshold:	No data available
pH value:	No data available
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
Vapor pressure:	No data available
Vapor density:	No data available
Density:	No data available
Water solubility:	at 68 °F: insoluble
Partition coefficient: n-octanol/water:	Bisphenol-A-epichlorhydrine resin, Molar mass: $\geq 700 \geq 3 \log P(o/w)$
Auto-ignition temperature:	No data available
Thermal decomposition:	> 140 °F
Additional information:	No data available

10. Stability and reactivity

Reactivity:	refer to section 10.3
Chemical stability:	Sensitive to heat and warmth. Stable under recommended storage conditions. (storage temperature -0.4 °F")
Possibility of hazardous reactions	In case of warming: Polymerization along with heat production. Fabric with matrix, Layer thickness >10 mm, Caution: While curing will be generated: heat (exothermic reaction)
Conditions to avoid:	Warmness.
Incompatible materials:	Strong oxidizing agents, strong alkalis, amines.
Hazardous decomposition products:	In case of warming: Toxic gases and vapors. In case of fire may be liberated: Hydrochloric gas, carbon monoxide and carbon dioxide.
Thermal decomposition:	> 140 °F

SAFETY DATA SHEET

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

Revision date: 3/22/2018

Version: 11

Language: en-US

Date of print: 5/24/2018

ottobock. 616B - Collective Data Sheet for Prepreg materials

Material number 616B

Page:

6 of 8

11. Toxicological information

Toxicological tests

Toxicological effects:

- 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.

Symptoms

In case of ingestion: Swallowing is not regarded as a possible way of exposition.
After contact with skin: Causes skin irritation.
May cause an allergic skin reaction.
Repeated exposure may cause skin dryness or cracking, due to defatting properties.
Other symptoms: Reddening,
After eye contact: Causes serious eye irritation.

12. Ecological information

Ecotoxicity

Aquatic toxicity:

- Toxic to aquatic life with long lasting effects.
- Bisphenol-A-(epichlorhydrin) epoxy resin (molecular weight ≤ 700):
 - Algae toxicity:
EC50 algae: 220 mg/L/96h.
 - Daphnia toxicity:
EC50 Daphnia magna: 1,1 - 3,6 mg/L/24h.
 - Fish toxicity:
LC50 Oncorhynchus mykiss: 1,5 - 7,7 mg/L/96h.
- Bisphenol-A-epichlorhydrine resin, Molar mass: ≥ 700 :
 - Algae toxicity:
IC50 algae: 1-10 mg/L/72h.
 - Daphnia toxicity:
EC50 Daphnia magna: 3,6 mg/L/24h.
 - Fish toxicity:
LC50 Oncorhynchus mykiss: 2,4 mg/L/96h.

SAFETY DATA SHEET

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

Revision date: 3/22/2018

Version: 11

Language: en-US

Date of print: 5/24/2018

ottobock.

616B - Collective Data Sheet for Prepreg materials

Material number 616B

Page: 7 of 8

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: Special waste. Incinerate according to applicable local, state and federal regulations.

Contaminated packaging

Recommendation: Special waste. Incinerate according to applicable local, state and federal regulations.

14. Transport information

USA: Department of Transportation (DOT)

Proper shipping name: Not restricted

Sea transport (IMDG)

Proper shipping name: Not restricted

Marine pollutant: not applicable

Air transport (IATA)

Proper shipping name: Not restricted

Further information

No dangerous good in sense of these transport regulations.

15. Regulatory information

National regulations - U.S. Federal Regulations

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

TSCA Inventory: listed; EPA flags XU

TSCA HPVC: not listed

Epichlorhydrin/Bisphenol A Epoxy Resin:

TSCA: listed - Flags: XU

Bisphenol-F-epichlorhydrine resin:

TSCA Inventory: listed; UVCB; EPA flags XU

TSCA HPVC: not listed

Bisphenol A - 4-tert-Butylphenol - Epichlorhydrin polymer:

TSCA Inventory: listed; EPA flags XU

TSCA HPVC: not listed

National regulations - Great Britain

Hazchem-Code: -

SAFETY DATA SHEET

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

Revision date: 3/22/2018

Version: 11

Language: en-US

Date of print: 5/24/2018

ottobock.

616B - Collective Data Sheet for Prepreg materials

Material number 616B

Page:

8 of 8

16. Other information

Text for labeling: See information supplied by the manufacturer.
Contains 10 - 25 % Bisphenol A epoxy resin (molecular-weight < 700), 5 - 10 % Epichlorhydrin/Bisphenol A Epoxy Resin, 1 - 2.5 % Bisphenol-F-epichlorhydrine resin, < 1 % Bisphenol A - 4-tert-Butylphenol - Epichlorhydrin polymer. Safety data sheet available on request.

Hazard rating systems:



NFPA Hazard Rating:

Health: 1 (Slight)

Fire: 1 (Slight)

Reactivity: 0 (Minimal)

HMIS Version III Rating:

Health: 1 (Slight)

Flammability: 1 (Slight)

Physical Hazard: 0 (Minimal)

Personal Protection: X = Consult your supervisor

HEALTH	1
FLAMMABILITY	1
PHYSICAL HAZARD	0
	X

Reason of change: Changes in section 1.3: Corporate headquarters

Date of first version: 10/27/2002

Department issuing data sheet

Contact person: see section 1: Dept. 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.