

COMPANY INFORMATION

COMPANY NAME: ORTHO SPECIALTIES
COMPANY ADDRESS: 3820 OHIO AVE - SUITE 15
 ST. CHARLES, IL 60174
COMPANY PHONE: 630-443-0225
COMPANY FAX: 630-443-0224
COMPANY WEB ADDRESS: www.orthospecialties.com

ELASTIC MATERIAL (AMBER/CLASS II)

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1 – PRODUCT IDENTIFICATION

PRODUCT NAME: Polyisoprene rubber (K-100 amber)

PRODUCT USE: Orthodontic use, intraoral and extraoral use

2 – COMPOSITION INFORMATION ON INGREDIENTS

CHEMICAL NAME 1,3 Butadiene, 2- Methyl, Homopolymer

NONHAZARDOUS COMPONENTS:

Natural Rubber	95-97%
Sulfur	0-1%
Zinc Oxide	0-1%
Polymeric Hindered Phenol	1-2%
Carbamate derivative	0-1%

3 – HAZARDS IDENTIFICATION

Based upon data this product is not hazardous under OSHA hazard communication (29 CFR 1910.1200) The nonhazardous components of this product meet FDA 21 CFR 177.26

4 – FIRST-AID MEASURES

4.1 INHALATION:
 No specific intervention is indicated as the compound is not likely to be hazardous by inhalation. Consult a physician if necessary. If exposed to fumes from overheating or combustion, move to fresh air. Consult a physician if symptoms persist.

4.2 SKIN CONTACT:
 Allergic reactions may occur in some people. Consult a physician if symptoms persist.

4.3 EYE CONTACT:
 Flush thoroughly with water, consult a physician

4.4 Ingestion: While ingestion of large enough quantities to cause health effects is unlikely, consult a physician if it occurs.

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5 – FIRE FIGHTING PROCEDURES

5.1 SUITABLE EXTINGUISHING MEDIA:
 Foam, Dry Chemical or water.

5.2 UNSUITABLE EXTINGUISHING MEDIA: N/A

5.3 PARTICULAR HAZARDS:
 When exposed to flame, emits oxides of carbon and other acrid fumes such as sulfur dioxide and carbon monoxide. No explosive hazards

5.4 PROTECTIVE EQUIPMENT FOR FIRE FIGHTERS:
 Wear self-contained breathing apparatus.

6 – ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS: N/A

6.2 ENVIRONMENTAL PRECAUTIONS: N/A

6.3 CLEANING METHODS:
 Dispose of in accordance with state, local, and federal regulations

7 – HANDLING & STORAGE

7.1 HANDLING: N/A

7.2 STORAGE: Keep closed to avoid contamination.

7.3 STORAGE CONDITIONS:
 Store at room temperature. Do not overexpose to light.

8 – EXPOSURE CONTROL/PERSONAL PROTECTION

FDA Label law requires labeling of medical devices with natural rubber latex in them. The warning reads "Caution: This product contains natural rubber latex with may cause allergic reaction".

Workers exposed to latex gloves and other medical products containing natural rubber latex may develop allergic reactions such as skin rashes, hives, eye or sinus symptoms, asthma and (rarely) shock.

Persons allergic to fruits or persons with spina bifida may be allergic to natural rubber.

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9 – PHYSICAL AND CHEMICAL PROPERTIES

9.1 Form: Solid
 Color: Colored
 Odor: Rubber
 9.2 Change of State:
 Melting Point/Range:
 Boiling Point:
 9.3 Flash Point
 9.4 Ignition Point:
 9.5 Vapor Pressure (20°C): N/A
 9.6 Density (20°C): .95
 9.7 Solubility in: Water (20°C): N/A
 Organic Solvent (20°C):
 9.8 PH-Value (at 10g/1H2O): N/A
 9.10 Viscosity (20°C): N/A

10 – STABILITY AND REACTIVITY

10.1 Thermal Decomposition: Stable
 10.2 Conditions to Avoid:
 High temperatures. Flames cause oxides of carbon
 10.3 Materials to Avoid: N/A
 10.4 Hazardous Decomposition Products: N/A.

11 – TOXICOLOGICAL INFORMATION

11.1 Oral Toxicity: N/E
 11.2 Inhalation: N/E
 11.3 Skin Irritation: N/E
 11.4 Sensitization: See Section 8
 11.5 Eye Irritation: N/E
 11.6 Further Details: See Section 8

12 – ECOLOGICAL INFORMATION

12.1 Acute Toxicity in Fish (LC-50/48h)
 12.2 Bacteria Toxicity (EC-0):
 12.3 Biodegradability:
 12.4 Further Details:

13 – DISPOSAL CONSIDERATIONS

13.1 Product: In accordance with state, local, and federal regulations
 13.2 Packaging: In accordance with state, local, and federal regulations
 13.3 Waste Disposal Code: In accordance with state, local, and federal regulations

14 – TRANSPORT INFORMATION

14.1 Overland Transport ADR/RID/GGVS/GGVE:
 14.2 Sea Transport GGVSEA/IMDG-Code:
 14.3 Air Transport ICAO/IATA-DGR:
 14.4 Inland Waterway Transport ADNR:
 14.5 Further Details:

15 – REGULATORY INFORMATION

Preparation as defined by the (German) Chemicals Act (dated 4/03/1990).

15.1 Labeling:
 Product Contains:
 Danger Symbol:
 R-Sentences R36/37/38:
 S-Sentences S26:
 S-Sentences S28:

15.2 National Regulation:
 VbF:
 TA-Air:
 Water Pollution 1:

16 – OTHER INFORMATION

16.1
 The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. Therefore, it should not be construed as guaranteeing specific properties.

16.2 Revision Date: November 28, 2006