

Document number:	AR/TH-MS-002b	Next Updated:	A/1
Updated number:	A/0	Updated by:	Jenny He
Date of updated:		Approved by:	
Date of approval:	Jan,1 st ,2010		

1. Product and Company Identification

Company Name: Astar Orthodontics Inc.	Product Grade/ Name: Polyisoprene(PI) rubber (Natural latex rubber)
Address: Suite1503, Lidu#1 Mansion, Lane#500, South Zhongshan Rd. Section1	Chemical Name: 1,3 Butadiene, 2-Methyl, Homopolymer
City: Shanghai	Product Use : Latex Intral oral and extra oral elastics
Country: China	Indication of use: For Orthodontic treatment only. This product is used by patients who need to follow doctor's instructions.
Telephone: +86-21-6303 1017	
E-mail: service@astar-ortho.com.cn	

2. Composition/Information on Ingredients

All components are non-hazardous				
Material	CAS Number	%(Range)	ACGIH-TLV*	OSHA-PEL*
Natural Rubber	NA	95~97	NA	NA
Sulfur	NA	0~1.0	NA	NA
Zinc oxide	NA	0~1.0	NA	NA
Polymeric hindered phenol	NA	1.0~2.0	NA	NA
Carbamate derivative	NA	0~1.0	NA	NA

*8-hour TWA.

3. Hazard Identification

Made by natural rubber which is widely used in dental field to be proved safe enough, does not contain hazardous or volatile substance.
No particular hazards known. However, overexposure to thermal decomposition may produce potentially hazardous dust or fume which can be inhaled, swallowed, or come in contact with skin, eyes, or mucous membranes.
Potential Environmental Effects : NA

4. First Aid Measures

Routes of Exposure	First Aid Measures
Eye contact	Flush well with running water to remove particulates and get medical attention.
Skin contact	Rubber allergic reactions may occur in some people. Consult a physician if symptoms persist.
Inhalation	If exposed to fumes overheating or combustion, move to fresh air. If condition continues, consult physician.
Ingestion	Seek medical help if large quantities of material have


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	been ingested.
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5.Fire Fighting Measures		
Flashpoint & Method: ° C/° F N/A	Flammable(Explosive)Limits in air LEL: N/E UEL: N/E	Auto ignition Temperature NA
Flame Propagation or Burning NA	Properties contributing to fire intensity NA	Flammability classification Health-, Flammability-,Reactivity
Extinguishing Media Dry chemical,water,foam		Extinguishing media to avoid NA
Protection and procedures for firefighters overexposure to thermal decomposition may produce potentially hazardous dust or fume. Wear self-contained breathing apparatus.		Unusual fire and explosion NA

6.Accidental Release Measures
Containment Techniques: N/A
Spill/Leak Clean-up procedures and equipment: Sweep up with mechanical means. Dispose of in accordance with state,local or federal regulation.
Environment Precautions: N/A
Special Instructions: N/A

7.Handling and Storage
Handling No special cares are requested. Keep away from flame or excessive heat.
Storage Keep the package and containers closed, and stored at room temperature. Avoid the corrosive gases.Keep away from sunlight. Shelf life:2years.

8.Exposure Control/Personal Protection
EC regulation 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.

9.Physical and Chemical Characteristics	
Appearance and Odor	Solid, Rubber Odor
Physical State:	Solid

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Solubility in Water(20 ° C):	Does not soluble
Solubility in Organic Solvent(20 ° C):	Does not soluble
Melting Point/Range:	NA
Boiling Point:	NA
Flash Point:	NA
Ignition Point:	NA
Vapor Pressure(20°C):	NA
Density(20°C):	.95
PH Value (at 10g/1H zO):	NA
Viscosity (20°C)	NA

10.Stability and Reactivity

Incompatibility (Materials to Avoid) N/A	
Stability? <input checked="" type="checkbox"/> Stable <input type="checkbox"/> Unstable	Conditions to Avoid High temperature. Flames cause oxide of carbon.
Hazardous Decomposition Products: By fire, oxides of carbon when burned	
Hazardous Polymerization? <input type="checkbox"/> May Occur <input checked="" type="checkbox"/> Will not Occur	

11.Toxicological Information

No toxic effect would be expected from exposure to the solid form of products.
Overexposure to fumes or dust generated during flume may or may cause adverse health effects.
This material contains rubber, which for some individuals, could result in development of rubber sensitization.

12.Ecological Information

Biodegradability: N/D
Biodaccumulation: N/D
Follow the local regulation for non-hazardous rubber materials.

13.Disposal Considerations

Regulations:
Disposal as per medical devices solid wastage in accordance with local regulations.
Properties(Physical/Chemical) Affecting Disposal
NA
Follow instructions under points6 and 12.



14.Transport Information

Technical Shipping Name: Not regulated
Freight Class Bulk: N/A
Freight Class Package: N/A

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Hazard Class or Division: Non-Hazardous
Further Details: Product is not considered dangerous for transport.

15.Regulatory Information
European Community: assigned to ClassIIa by Medical Device Directive 93/42 EEC
Label information follow the EN980: 2008 «Symbols for use in the labelling of medical devices»

16.Other Information
<p>This 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.</p> <p>The information in this MSDS is based on technical data that we believe to be reliable. Astar assumes no responsibility and makes no warranties, expressed or implied, regarding the accuracy or currency of any data so provided. Since conditions of storage, use, and disposal of this products are beyond our control, we make no warranties, expressed or implied, and assume no liability in connection with the use of this product.</p> <p>Attention for final products: For Orthodontic treatment only. This product is for intra-oral and extra- oral used, used by patients who need to follow doctor’s instructions. The product contain natural rubber latex in them. The warning reads :</p> <p>“  Caution: This product contains natural rubber latex with may cause allergic reaction”.</p>
<p>N/A=not applicable NA= not available N/D= not determined mg/m³= milligrams per cubic meter C = ceiling PEL = permissible exposure limit</p>