

Document number:	AR/TH-MS-007	Next Updated:	A/1
Updated number:	A/0	Updated by:	Jenny He
Date of updated:		Approved by:	
Date of approval:	Sept.,16 <sup>th</sup> ,2015		

**1. Product and Company Identification**

Company Name: <b>Astar Orthodontics Inc.</b>	Product Grade/ Name: <b>Aluminum Oxide (Al<sub>2</sub>O<sub>3</sub>, &gt;99.998%)</b>
Address: Suite1503, Lidu#1 Mansion, Lane#500, South Zhongshan Rd.	Product Use: <b>Sapphire Brackets</b>
City: Shanghai	
Country: China	
Telephone: +86-21-6303 1017	
E-mail: service@astar-ortho.com.cn	
Indication of use: For Professional Orthodontic treatment only.	

**2. Composition/Information on Ingredients**

Aluminum Oxide, Al <sub>2</sub> O <sub>3</sub>
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**3. Hazard Identification**

Made by aluminum oxide which is widely used in dental field to be proved safe enough, does not contain hazardous or volatile substance. Non-hazardous for human body and health. However, subsequent operations such as grinding, heat treating, or processing in any other fashion may produce potentially hazardous dust or fume which can be inhaled, swallowed, or come in contact with skin, eyes, or mucous membranes.
Non-hazardous for human body and health, a simulating effect on the mucous membranes and upper respiratory tract.
Potential Environmental Effects : NA

**4.First Aid Measures**

Routes of Exposure	First Aid Measures
Eye contact	Flush well with running water or saline rinse, to remove particulates and get medical attention.
Skin contact	Wash area well with soap and running water.
Inhalation	Remove to fresh air, if condition continues, consult physician.
Ingestion	Drink enough warm water to emetic. Seek medical help if large quantities of material have been ingested.

**5.Fire Fighting Measures**

N/A
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**6.Accidental Release Measures**

Isolation leakage polluted area, restricting access. Recommended emergency personnel wearing a dust mask (full face mask), wear protective clothing. To avoid dust, carefully scan, bag placed transfer to a safe place. If large spills, cover with plastic sheeting, canvas. Recycling or collection shipped to the waste disposal sites.
Special Instructions N/A

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**7. Handling and Storage**

**Handling**

Closed operation, local exhaust ventilation. The operator must go through specialized training, and strictly abide by the rules. The proposed operating personnel wearing self-absorption filter respirators, wearing chemical protective safety glasses, wear protective overalls on infiltration, wear rubber gloves. Avoid generating dust. Avoid contact with oxidants. Handle with care unloading, packaging to prevent breakage. With spill contingency processing equipment. The empty containers may be harmful residues.

**Storage**

Store in a cool, dry, well ventilated warehouse. Keep away from fire and heat source. Keep container closed. And oxidizer stored separately to avoid mixing reservoir. The storage area should be equipped with suitable material spill.

**8. Exposure Control/Personal Protection**

Material	CAS Number	%(Range)	ACGIH-TLV	OSHA-PEL
Aluminum Oxide	1344-28-1	99.94	10 mg/m <sup>3</sup>	15 mg/m <sup>3</sup> (Total Dust)
Personal Protective Equipment: Respiratory Protection: if fumes, misting or dust conditions occurs and exceeds applicable OSHA Standards. Personal Protection: Respiratory: if fumes, misting or dust conditions occur and exceed applicable OSHA Standards, provide NIOSH approved air-supplied respirators.				
Eye Protection	Recommend approved safety glasses when grinding, etc.			
Hand Protection	Rubber Gloves: As required.			
Body Protection	Work clothes as required.			

**9. Physical and Chemical Characteristics**

Appearance and Odor	White odorless powder.
Physical State: Solid	Solubility in Water: Does not soluble, slightly soluble in inorganic acid
Boiling Point:	5000°C
Melting Point:	2043°C
Specific Gravity:	3970kg/m <sup>3</sup>
Bending Strength:	180MPa
Hardness(Knoop):	1370kg/mm <sup>2</sup>
Freezing Point:	NA
Flash Point:	NA
Autoignition	NA
Density:	NA
Viscosity:	NA

**10. Stability and Reactivity**

Stability? <input checked="" type="checkbox"/> Stable <input type="checkbox"/> Unstable	Conditions to Avoid Avoid contact with moist air and strong oxidizing
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	agents.
Hazardous Polymerization? <input type="checkbox"/> May Occur <input checked="" type="checkbox"/> Will not Occur	Conditions to Avoid N/A
Incompatibility Material to Avoid: Avoid contact with moist air and strong oxidizing agents.	

<b>11.Toxicological Information</b>
No toxic can be found in exposure to the powder form of the products under normal circumstance. Prolonged, repeated exposure to fumes or dust generated during subsequent operation may or may cause adverse health effects associated with the listed constituents in excess of OSHA permissible exposure limits.

<b>12.Ecological Information</b>
Biodegradability: N/D
Biodaccumulation: N/D
Follow the local regulation for non-hazardous metallic materials.

<b>13.Disposal Considerations</b>
Regulations: Dump in accordance with local regulations.
Properties(Physical/Chemical) Affecting Disposal NA
Follow instructions under points6 and 12.

<b>14.Transport Information</b>
Technical Shipping Name: Not regulated
Freight Class Bulk: N/A
Freight Class Package: N/A
Hazard Class or Division: Non-Hazardous

<b>15.Regulatory Information</b>
European Community: assigned to Class II a by Medical Device Directive 93/42 EEC
U.S.A : assigned to Class I Medical Devices by U.S. Food and Drug Administration(FDA)
Label information follow the EN980: 2008 《Symbols for use in the labelling of medical devices》

<b>16.Other Information</b>
Attention: <ol style="list-style-type: none"> <li>The product should be sterilized before used. 75% alcohol is recommended.</li> <li>There should be no change on the color and the shape of the products after sterilization, as well as no impact to the treatment.</li> <li>Disposable only.</li> <li>For professional use only.</li> </ol>

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5. Single use to the correspondent tooth only. Please follow the advice on the product label. Mixed or wrongly placement of the tubes might lead to unexpected problem in clinic .

N/A=not applicable NA= not available N/D= not determined

mg/m<sup>3</sup>= milligrams per cubic meter C = ceiling PEL = permissible exposure limit