

1. PRODUCT AND COMPANY IDENTIFICATION
1.1 Product Identifier

Product Name: Silkon Plus TM
Common Name: Composite Brackets/ Cosmetic Brackets
Material: Polycarbonate
Restrictions on Use: American Orthodontics' products are used for the treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist. Federal law restricts this device to use by or on the order of a dentist or orthodontist.

EC No.: 236-675-5 (Titanium Oxide)
 231-784-4 (Barium Sulfate)

REACH Registration No.: 01-2119489379-17-0XXX (Titanium Oxide)
 01-2119491274-35-00XX (Barium Sulfate)

CAS No. / IUPAC: 13463-67-7 (Titanium Oxide)
 7727-43-7 (Barium Sulfate)

1.2 Relevant Identified Uses/ Uses Advised Against

Relevant identified uses: Dental/Orthodontic use only
Uses advised against: Not for Consumer use. Please see "Restrictions on Use"

1.3 Details of the Supplier of the Safety Data Sheet

Company Name:
 American Orthodontics
 3524 Washington Avenue
 Sheboygan, WI 53081
 Phone: 920-457-5051
 Fax: 920-457-1485

E-mail: info@americanortho.com
National Contact: Safety Department

1.4 Emergency Telephone Number

Emergency Response Number:
 920-457-5051
 Only available during office hours: 8:00AM – 5:00PM (Central Time)
 Language of Phone Service: English

2. HAZARDS IDENTIFICATION
General Hazard Statement:

This product is a manufactured article as defined under REACH. No labeling is required for finished product.

This product is classified as "articles" and do not constitute a hazardous material in solid form und the definitions of the OSHA Hazard Communication Standard (29CFR1910.1200). Any articles manufactured from these solid products would be generally classified as non-hazardous. However some hazardous elements contained in these products may be emitted under certain processing conditions. Products in the solid stat present no fire or explosion hazards.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient(s)</u>	<u>CAS No.</u>	<u>EC No.</u>	<u>Wt. % Content (or Range)</u>
Titanium dioxide	13463-67-7	236-675-5	0.1-1
Barium sulfate	7727-43-7	231-784-4	5-10

4. FIRST-AID MEASURES

Inhalation: Move to fresh air in case of accidental inhalation of fumes from overheating or combustion. When symptoms persist or in all cases of doubt, seek medical advice.

Ingestion: Do not induce vomiting without medical advice. When symptoms persist or in all cases of doubt, seek medical advice.

Eyes: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If eye irritation persists, seek medical attention.

Skin: Wash off with soap and plenty of water. If skin irritation persists seek medical attention.

5. FIRE AND EXPLOSION HAZARDS

5.1 Extinguishing Media

Suitable Extinguishing Media:

- Carbon dioxide blanket, water spray, dry powder, foam

5.2 Special Exposure Hazards from Substance/Mixture

Hazardous Combustion Products:

- Carbon dioxide, carbon monoxide, oxides of nitrogen, other hazardous materials, and smoke are all possible.

5.3 Advice for Firefighters

- Use full-face self-contained breathing apparatus (SCBA) in positive pressure mode to prevent inhalation of airborne contaminants and hazardous combustion products.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment & Emergency Procedures

Wear approved personal protective clothing during cleanup, such as impervious gloves, boots, and coveralls.

6.2 Environmental Precautions

Product should not be released into the environment. Keep away from drains, water courses, or soil.

6.3 Methods & Material for Containment & Cleaning Up

Clean up promptly by sweeping or vacuuming area. Package all materials in plastic, cardboard, or metal containers for disposal. Refer to Section 13 for proper disposal methods.

6 HANDLING AND STORAGE

7.1 Precautions for Safe-Handling

Take measures to prevent the buildup of electrostatic charge. Heat only in areas with appropriate exhaust ventilation.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

Keep containers dry and tightly closed to avoid moisture absorption and contamination. Store in a cool, dry place.

7.3 Advice on General Hygiene

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and the end of workday.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control Parameters

Exposure Limit(s):

Components	Value	Exposure Time	Exposure Type	List
Barium Sulfate	10 mg/m ³	Time Weighted Average (TWA):		ACGIH
	5 mg/m ³	Recommended Exposure Limit (REL):	Respirable	NIOSH
	10 mg/m ³	Recommended Exposure Limit (REL):	Total	NIOSH
	5 mg/m ³	PEL:	Respirable fraction.	OSHA Z1
	15 mg/m ³	PEL:	Total dust.	OSHA Z1
	5 mg/m ³	Time Weighted Average (TWA):	Respirable fraction.	OSHA Z1A
Titanium Dioxide	10 mg/m ³	Time Weighted Average (TWA):	Total dust.	OSHA Z1A
	15 mg/m ³	PEL:	Total dust.	OSHA Z1
	10 mg/m ³	Time Weighted Average (TWA):	Total dust.	OSHA Z1A
	10 mg/m ³	Time Weighted Average (TWA):	As Ti	MX OEL
	20 mg/m ³	Short Term Exposure Limit (STEL):	As Ti	MX OEL

8.2 Exposure Controls

Routes of Exposure: Inhalation, Ingestion, Skin Contact

Acute Exposure:

Inhalation: Resin particles, like other inert materials, can be mechanically irritating

Ingestion: May be harmful if swallowed

Eyes: Resin particles, like other inert materials, can be mechanically irritating to eyes

Skin: Experience shows no unusual dermatitis hazard from routine handling

Chronic Exposure: Reference Section 11

Medical Conditions Aggravated by Exposure: None Known

8.2.1 Appropriate Engineering Controls

Heat only in areas with appropriate exhaust ventilation. Provide appropriate exhaust ventilation at machinery.

8.2.2 Personal Protective Equipment

8.2.2.1 Eye & Face Protection

- Safety glasses with side shields

8.2.2 Skin Protection

Hand Protection

- Protective gloves

Other Skin Protection

- Long sleeved clothing

8.2.2.3 Respiratory Protection

- No personal respiratory equipment normally required

8.2.2.4 Additional Protective Measures

- Safety shoes

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Basic Physical & Chemical Properties

Appearance:	White Solid
Odor:	Very Faint
Odor Threshold:	N/A
pH:	N/A
Melting Point/Freezing Point:	Not determined
Initial Boiling Point & Boiling Range:	N/A
Flash Point:	N/A
Evaporation Rate:	N/A
Flammability (solid, gas):	N/A
Solubility(ies):	Insoluble

10 STABILITY AND REACTIVITY

Stability: Stable

Hazardous Polymerization: Will not occur

Conditions to Avoid: Keep away from oxidizing agents and open flame. To avoid thermal decomposition, do not overheat.

Incompatible Materials: Incompatible with strong acids and oxidizing agents

Hazardous Decomposition Products: Carbon Dioxide (CO₂); Carbon Monoxide (CO); Oxides of Nitrogen (NO_x), other hazardous materials and smoke are all possible.

11 TOXICOLOGICAL INFORMATION

This mixture has not been evaluated as a whole for health effects. Exposure effects listed are based on existing health data for the individual components which comprise the mixture.

Toxicity Overview:

This product contains the following components which in their pure form have the following characteristics:

<u>CAS No.</u>	<u>Chemical Name</u>	<u>Effect</u>	<u>Target Organ</u>
13463-67-7	Titanium Dioxide	Systemic effects	Respiratory system
7727-43-7	Barium Sulfate	Irritant	Respiratory system
		Systemic effects	Eyes, respiratory system.

Carcinogenicity:

This product contains the following components which in their pure form have the following carcinogenicity data:

<u>CAS No.</u>	<u>Chemical Name</u>	<u>OSHA</u>	<u>*IARC</u>	<u>NTP</u>
13463-67-7	Titanium Dioxide	No	2B	No

**IARC Carcinogen Classification:*

2B – The component is possibly carcinogenic to humans.

12 ECOLOGICAL INFORMATION

12.2 Toxicity

Chemicals are not readily available as they are bound within the polymer matrix.

12.3 Persistence and Degradability

Not readily biodegradable

12.4 Bio accumulative Potential

Chemicals are not readily available as they are bound within the polymer matrix.

13 DISPOSAL CONSIDERATIONS

Product: Like most thermoplastic plastics the product can be recycled. Where possible recycling is preferred to disposal or incineration. The generator of waste material has the responsibility for proper waste classification, transportation and disposal with accordance applicable federal, state/provincial and local regulations.

Contaminated Packaging: Recycling is preferred when possible. The generator of waste material has the responsibility for proper waste classification, transportation and disposal with accordance applicable federal, state/provincial and local regulations.

14 TRANSPORTATION INFORMATION

Not regulated for transport.

15 REGULATORY INFORMATION**15.2 Safety, health and environmental regulations/legislation specific for the substance or mixture****National Regulations (USA):**

OSHA Status: Classified as hazardous based on components.

TSCA Status: All components of this product are listed on or exempt from the TSCA Inventory.

U.S. EPA CERCLA Hazardous Substances (40 CFR 302):N/A

California Proposition 65: N/A

SARA Title III Section 302 Extremely Hazardous Substance:

Unless specific chemicals are identified under this section, this product is Not Applicable under this regulation.

SARA Title III Section 313 Toxic Chemicals: Unless specific chemicals are identified under this section, this product is Not Applicable under this regulation.

Canadian Regulations:

National Pollutant Release Inventory (NPRI): N/A

WHMIS Classification: D2A

DSL: All components of this product are on the Canadian Domestic Substances List (DSL) or are exempt.

National Inventories:

Australia AICS: Listed

China IECS: Listed

Europe EINECS: Listed

Japan ENCS: Not determined

Korea KECI: Listed

Philippines PICCS: Listed

15.3 Chemical Safety Assessment:

No chemical safety assessment has been carried out for this substance/mixture by the supplier.

16 ADDITIONAL INFORMATION**16.2 Indication of changes/revision to SDS:**

1. New format
2. Inclusion of EC Requirements
3. *Revision Date:* 09/16/2015

16.3 Abbreviations and acronyms:

None

16.4 Key literature references and sources for data

1. Guidance on the Compilation of Safety Data Sheets; European Chemical Agency (ECHA); Version 2.1, February 2014
2. Regulation (EC) No 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling, and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

16.5 Classification and procedure used to derive classification for mixtures according to Regulation (EC) 1272/2008[CLP]:

None

Some of the information presented and conclusions drawn herein are from sources other than direct test data on the product itself. The information in the SDS was obtained from sources that we believe are reliable and is believed to be valid and accurate. American Orthodontics, however, makes no warranty, express or implied, regarding its correctness of the information provided. The conditions or method of handling, storage, use and disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage, or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. If the product is used as a component in another product or used in a way other than recommended by the Company, this SDS information may not be applicable. **Reasonable safety precautions must always be observed.**