

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product Identifier

Product Name: Atmos Thermoforming Material BRX and TMP
Common Name: Supplies
Material: Polypropylene
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.: None
REACH Registration No.: None
CAS No. / IUPAC: None

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 under the definitions of the OSHA Hazard Communication Standard (29CFR1910.1200). Any articles manufactured from these solid products would be generally classified as non-hazardous.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient(s)</u>	<u>CAS No.</u>	<u>EC No.</u>	<u>Wt. % Content (or Range)</u>
Polypropylene	Proprietary		96-100%
Modifiers/Additives	Proprietary		0-4%

4. FIRST-AID MEASURES

4.1 Description of First-Aid Measures

General Notes

As a solid, product is considered safe and non-hazardous

Inhalation

As a solid, product would not cause irritation to the nose, throat and respiratory tract

Skin Contact

Cool skin rapidly with cold water after contact with molten material.

Do not peel solidified product off the skin.

Burns must be treated by a physician.

Eye Contact

If molten material contacts the eye, immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention immediately.

Ingestion/Swallowing

Seek medical advice.

4.2 Important Symptoms and Effects

The molten product can cause serious burns.

Notes to the Doctor:

Treat symptomatically.

5. FIRE AND EXPLOSION HAZARDS

5.1 Extinguishing Media

Suitable Extinguishing Media:

- Water spray
- Dry chemical
- Carbon dioxide (CO₂)

Extinguishing Media which should not be used:

Do not use a solid water stream as it may scatter and spread fire.

5.2 Special Exposure Hazards from Substance/Mixture

Hazardous Combustion Products:

No hazardous combustion products are known

5.3 Advice for Firefighters

Firefighting Methods:

Minimize dust generation and accumulation.

Special protective equipment for fire-fighters:

Wear an approved positive pressure self-contained breathing apparatus in addition to standard fire fighting gear.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment & Emergency Procedures

6.1.1 For Non-Emergency Personnel

Protective Equipment:

Wear appropriate personal protective equipment.

Emergency Procedure:

Local authorities should be advised if significant spillages cannot be contained.

6.2 Environmental Precautions

Avoid release to the environment.

6.3 Methods & Material for Containment & Cleaning Up

6.3.1 and 6.3.2 For Containment and Cleaning Up

Sweep up and shovel into suitable containers for disposal.

7. HANDLING AND STORAGE

7.1 Precautions for Safe-Handling

Protective Measures:

Measures to prevent fire and explosion:

Minimize dust generation and accumulation.

Advice on General Occupational Hygiene:

Wash thoroughly after handling.

Use only in area provided with appropriate exhaust ventilation.

Minimize dust generation and accumulation.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

Safe Storage Conditions

Keep tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control Parameters

No data available but non-toxic as supplied.

8.2 Exposure Controls

8.2.1 Appropriate Engineering Controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

8.2.2 Personal Protective Equipment

8.2.2.1 Eye & Face Protection

- Safety glasses
- Wear a face shield when working with molten material.

8.2.2 Skin Protection

Hand Protection

- Wear suitable gloves. When handling hot material, use heat resistant gloves.

Other Skin Protection

- Wear suitable protective clothing.

8.2.2.3 Respiratory Protection

Not ordinarily required. Use either an atmosphere-supplying respirator or an air-purifying respirator for particles.

Reference Section 5 for specific personal protective equipment advice

8.2.3 Environmental Exposure Controls

Adequate ventilation and/or engineering controls are required when the product is heated for processing. Ventilation is required to control dust concentration in air.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Basic Physical & Chemical Properties

Appearance:	Solid
Color	Colorless
Odor:	Slight
Odor Threshold:	Not Determined
pH:	Not Determined
Melting Point/Freezing Point:	> 100 °C
Initial Boiling Point & Boiling Range:	Not Determined
Flash Point:	300°C, Combustible Solid
Evaporation Rate:	Not Determined
Flammability (solid, gas):	May form combustible dust concentrations in air during processing, handling or other means
Upper/Lower Flammability or Explosive Limits:	Not Determined
Vapor Pressure:	Not Determined
Vapor Density:	Not Determined
Relative Density:	< 1 g/cc
Solubility(ies):	Negligible
Partition Coefficient: n-octanol/water):	No Data Available
Auto-Ignition Temperature:	390 °C
	Method: ASTM E659

Decomposition Temperature:	Thermal stability not tested. Low stability hazard expected at normal operating temperatures.
Viscosity:	Not Determined
Explosive Property:	No Data Available
Oxidizing:	No Data Available

10. STABILITY AND REACTIVITY

10.1 Reactivity

None reasonably foreseeable

10.2 Chemical Stability

Stable under normal conditions

10.3 Conditions of Instability

None reasonably foreseeable

10.4 Possibility of Hazardous Reactions

No dangerous reactions known

10.5 Conditions to Avoid

Minimize dust generation and accumulation

10.6 Incompatible Materials

Strong oxidizing agents

10.7 Hazardous Decomposition Products

Carbon Monoxide

Carbon Dioxide (CO₂)

10.8 Hazardous Polymerization

None reasonably foreseeable

11. TOXICOLOGICAL INFORMATION

11.1 Acute toxicity

Primary irritant effects:

On the skin: Molten material will produce thermal burns.

On the eyes: Molten material will produce thermal burns.

Oral LD-50 (rat): >5 g/kg practically nontoxic

Dermal LD-50 (rabbit): >2 g/kg practically nontoxic

12. ECOLOGICAL INFORMATION

12.1 Toxicity

No data available

12.2 Persistence and Degradability

No data available

12.3 Bio accumulative Potential

No data available

12.4 Mobility in Soil

No data available

12.5 Results of PBT and vPvB Assessment

- No data available
- 12.6 Other Adverse Effects**
No data available

13. DISPOSAL CONSIDERATIONS

- 13.1 Waste Treatment Methods**
Waste from residues: Dispose of in accordance with local regulations.

14. TRANSPORTATION INFORMATION

- 14.1 UN Number**
Not regulated as a dangerous good
- 14.2 UN Proper Shipping Name**
Not regulated as a dangerous good
- 14.3 Transport Hazard Class(es)**
Not regulated as a dangerous good
- 14.4 Packing Group**
Not regulated as a dangerous good
- 14.5 Environmental Hazards**
Not regulated as a dangerous good
- 14.6 Special Precautions for User**
Not
- 14.7 Transport in Bulk According to Annex II of MARPOL73/78 and the IBC Code**
Not applicable for product as supplied.

15. REGULATORY INFORMATION

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
OSHA Classification: nonhazardous
WHMIS (Canada) Status: non-controlled
- 15.2 Chemical Safety Assessment:**
No chemical safety assessment has been carried out for this substance/mixture by the supplier.

16. ADDITIONAL INFORMATION

- 16.1 Indication of changes/revision to SDS:**
Revision Date: 09/20/2024
The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and re-lease and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

16.2 Abbreviations and acronyms:

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

16.3 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

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.**