1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product Identifier

Product Name: Atmos Thermoforming Material
Common Name: Supplies
Material: Copolyester
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 INDENTIFICATION

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.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient(s)	CAS No.	EC No.	Wt. % Content (or Range)
Copolyester	Proprietary		100%

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 rubbed in eyes product is presumed to be mildly irritating

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

8.1Control 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.

8.2.2.4 Thermal Hazards

- xxxx

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:	Not Applicable, 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 (Estimated)
Solubility(ies):	Negligible
Partition Coefficient: n-octanol/water):	No Data Available
Auto-Ignition Temperature:	454 °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
Stable
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 Information on Toxicological Information

- Acute Toxicity
  Not classified based on available information.
  Oral toxicity: Remarks: No data available
  Inhalation toxicity: Remarks: No data available
  Dermal toxicity: Remarks: No data available
- Skin Corrosion
  Not classified based on available information.
  Remarks: No data available
- Serious Eye Damage/Irritation
  Not classified based on available information.
  Remarks: No data available
- Respiratory/Skin Sensitization
  Not classified based on available information.
  Remarks: No data available
- Germ Cell Mutagenicity
  Not classified based on available information.

- Carcinogenicity
  Not classified based on available information.
  Remarks: This information is not available
- Reproductive Toxicity
  Not classified based on available information.
  Remarks: No data available
- STOT-Single Exposure
  Not classified based on available information.
  Remarks: No data available
- STOT-Repeated Exposure
  Not classified based on available information.
  Remarks: No data available
- Aspiration Hazard
  Not classified based on available information.
  No data available
- Signs & Symptoms of Exposure

Inhalation:	Remarks: None known
Skin Contact:	Remarks: The molten product can cause serious burns
Eye Contact:	Remarks: The molten product can cause serious burns
Ingestion:	Remarks: None known

11.1.1 Acute Toxicity

Acute oral toxicity:	LD50 Oral (Rat): > 3,200 mg/kg Assessment: The substance or mixture has no acute oral toxicity
Acute dermal toxicity:	LD50 Dermal (Guinea pig): > 1,000 mg/kg Assessment: The substance or mixture has no acute dermal toxicity

11.1.2 Skin Corrosion

Species: Guinea pig
Exposure time: 24 h
Result: slight

11.1.3 Serious Eye Damage/Irritation

Species: Rabbit
Result: slight
Method: unwashed eyes
Species: Rabbit
Result: slight
Method: washed eyes

11.1.4 Respiratory/ Skin Sensitization

Test Type: Skin Sensitization
Species: Guinea pig
Result: non-sensitizing

11.1.5 Carcinogenicity

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA	No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.
NTP	No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

11.1.6 Reproductive Toxicity

Effects on fertility: Remarks: No data available

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to Fish:	LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Remarks: (highest concentration tested)
Toxicity to daphnia and other aquatic invertebrates:	LC50 (daphnid): > 100 mg/l Exposure time: 96 h Remarks: (highest concentration tested) LC50 (snail): > 100 mg/l Exposure time: 96 h Remarks: (highest concentration tested) LC50 (flatworm): > 100 mg/l Exposure time: 96 h Remarks: (highest concentration tested)

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

EU Regulations

Authorizations and/or restrictions on use:
Authorization:
Restrictions on use:

Other EU Regulations:

Information according to 1999/13/EEC about limitation of emissions of volatile organic compounds (VOC-Guideline):

National Regulations (USA):

xxx

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: 11/22/2019
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 Sub-stances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Haz-ardous 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 Sys-tem; 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 Organiza-tion; 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 Chemi-cals 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 Pre-vention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Oth-erwise 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 sub-stance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quanti-tative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concern-ing the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amend-ments 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