

Title: SmartTrack Aligner Material		MCO Number: SJ005129
Doc Number: D16285	Rev: A2	Last Print Date: 12/08/2015

MATERIAL SAFETY DATA SHEET



ALIGN TECHNOLOGY, INC.
2560 Orchard Parkway
San Jose, CA 95131
USA
(888) 822-5446

1. Product and Company Identification

Product Name: SmartTrack Aligner Material

Chemical Family: Multilayer aromatic thermoplastic polyurethane / copolyester.

Chemical Name: Multilayer aromatic thermoplastic polyurethane / copolyester.

2. Hazards Identification

Emergency Overview

Caution: Color: Natural

Form: solid Plastic film

Odor: Odorless.

Melted product is combustible and produces intense heat and dense smoke during burning. Toxic gases/fumes are given off during burning or thermal decomposition and may cause allergic skin and respiratory reaction. Contact with hot material will cause thermal burns.

Potential Health Effects

Primary Routes of Entry: Inhalation, Skin Contact, Eye Contact

Medical Conditions Aggravated by Exposure: Respiratory disorders

HUMAN EFFECTS AND SYMPTOMS OF OVEREXPOSURE

Inhalation

Acute Inhalation

For Product: SmartTrack Aligner Material

Thermoplastic Polyurethane (TPU) film is generally non-hazardous under ambient conditions as well as under recommended processing temperatures and conditions when following good manufacturing practices. However, as is common for all Diphenylmethane Diisocyanate (MDI)-based thermoplastic urethanes, if the material is subjected to temperatures above its decomposition temperature (482F / 250C in the case of this product), MDI may be liberated. The following effects reflect the potential health hazards associated with overexposure to MDI. Diisocyanate vapors or mist at concentrations above the TLV or PEL can irritate (burning sensation) the mucous membranes in the respiratory tract (nose, throat, lungs) causing runny nose, sore throat, coughing, chest discomfort, shortness of breath and reduced lung function (breathing obstruction). Persons with a preexisting, nonspecific bronchial hyperreactivity can respond to concentrations below the TLV or PEL with similar symptoms as well as asthma attack or asthma-like symptoms. Exposure well above the TLV or PEL may lead to bronchitis, bronchial spasm and pulmonary edema (fluid in lungs). Chemical or hypersensitivity pneumonitis, with flu-like symptoms (e.g., fever, chills), has also been reported. These symptoms can be delayed up to several hours after exposure. These effects are usually reversible.

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Chronic Inhalation

For Product: SmartTrack Aligner Material

In the event of material decomposition due to exceeding the decomposition temperature of this product, release of MDI may occur. As a result of previous repeated overexposures or a single large dose, certain individuals may develop sensitization to diisocyanates (asthma or asthma-like symptoms) that may cause them to react to a later exposure to diisocyanates at levels well below the TLV or PEL. These symptoms, which can include chest tightness, wheezing, cough, shortness of breath or asthmatic attack, could be immediate or delayed up to several hours after exposure. Extreme asthmatic reactions can be life threatening. Similar to many non-specific asthmatic responses, there are reports that once sensitized an individual can experience these symptoms upon exposure to dust, cold air or other irritants. This increased lung sensitivity can persist for weeks and in severe cases for several years. Sensitization can be permanent. Chronic overexposure to diisocyanates has also been reported to cause lung damage (including fibrosis, decrease in lung function) that may be permanent.

Skin

Acute Skin

For Product: SmartTrack Aligner Material

Contact with heated material can cause thermal burns.

Eye

Acute Eye

For Product: SmartTrack Aligner Material

Vapors released from thermal decomposition may cause irritation with symptoms of burning and tearing.

Carcinogenicity:

No Carcinogenic substances as defined by IARC, NTP and/or OSHA

3. Composition/Information on Ingredients

Hazardous components

This material is not hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

4. First aid measures

Eye contact

In case of contact, flush eyes with plenty of lukewarm water. Get medical attention if irritation develops.

Skin contact

Get medical attention if thermal burn occurs.

Inhalation

If inhaled, remove to fresh air.

Notes to physician

In the event of possible diisocyanate exposure: Eyes: Stain for evidence of corneal injury. If cornea is burned, instill antibiotic/steroid preparation as needed. Workplace vapors could produce reversible corneal epithelial edema impairing vision. Skin: Treat symptomatically as for thermal burn. Ingestion: Treat symptomatically. Inhalation: Treatment is essentially symptomatic. An individual having a pulmonary sensitization reaction to this material should be removed from further exposure to any diisocyanate.

5. Fire-fighting measures

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Suitable extinguishing media: Water, Foam, Dry chemical

Special Fire Fighting Procedures

Firefighters should be equipped with self-contained breathing apparatus to protect against potentially toxic and irritating fumes.

Unusual Fire/Explosion Hazards

Toxic and irritating gases/fumes may be given off during burning or thermal decomposition.

6. Accidental release measures

Spill and Leak Procedures

If molten, allow material to cool and place into an appropriate marked container for disposal.

7. Handling and storage

Storage period

Not Established

Handling/Storage Precautions

Handle in accordance with good industrial hygiene and safety practices. Wash thoroughly after handling. Avoid breathing dust. Containers should be kept tightly closed to prevent contamination.

Further Info on Storage Conditions

Protect equipment (e.g. storage bins, conveyors, dust collectors) with explosion vents.

8. Exposure controls/personal protection

TPU film in its supplied form is generally not hazardous; however, when the product is heated (i.e. during thermal processing extrusion), there is potential for the release of MDI vapors. If heated above decomposition temperatures, there is potential for release of MDI in addition to decomposition products (see section 10). The following exposure limits do not apply to the product in its supplied form; however, when the product is heated (i.e. during processing or thermal decomposition conditions), there is a potential for the release of 4,4'-diphenylmethane diisocyanate (MDI) vapors.

4,4'-Diphenylmethane Diisocyanate (MDI) (101-68-8)

US. ACGIH Threshold Limit Values

Time Weighted Average (TWA): 0.005 ppm

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Ceiling Limit Value: 0.02 ppm, 0.2 mg/m³

Industrial Hygiene/Ventilation Measures

During normal processing, use general dilution and local exhaust as necessary to control airborne vapors, mists, and dusts below appropriate airborne concentration standards/guidelines. Special ventilation and personal protective equipment (PPE) is required to control exposure to potentially harmful decomposition products whenever a TPU is heated to temperatures above its decomposition temperature.

Respiratory protection

NIOSH approved air-supplied respirator during die cleaning, high temperature processing or when thermal decomposition is suspected.

Hand protection

Wear heat resistant gloves when handling molten material.

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Eye protection

Safety glasses with side-shields

Skin and body protection

No special skin protection requirements during normal handling and use.

Additional Protective Measures

Employees should wash their hands and face before eating, drinking, or using tobacco products. Educate and train employees in the safe use and handling of this product. Purgings should be collected as small flat thin shapes or thin strands to allow for rapid cooling.

9. Physical and chemical properties

Form: solid

Appearance: Plastic film

Color: Natural

Odor: Odorless

pH: not applicable

Melting Point: > 100 °C (212 °F)

Flash point: > 210 °C (410 °F)

Lower explosion limit: not applicable

Upper explosion limit: not applicable

Vapour pressure: not applicable

Specific Gravity: 1.0 - 1.3

Solubility in Water: insoluble

Autoignition temperature: not applicable

Softening point: ca. 99 °C (210.2 °F)

10. Stability and reactivity

Hazardous Reactions

Hazardous polymerisation does not occur.

Stability

Stable

Materials to avoid

None known.

Conditions to avoid

None known.

Hazardous decomposition products

By Fire and Thermal Decomposition: Carbon Dioxide; hydrogen cyanide; 4,4'-Diphenylmethane Diisocyanate (MDI); Aldehydes, Carbon monoxide, Nitriles, nitrogen oxides (NO_x), Hydrocarbons, other potentially toxic fumes

11. Toxicological information

Toxicity Data for SmartTrack Aligner Material

Toxicity Note

No data available for this product.

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12. Ecological information

Ecological Data for SmartTrack Aligner Material

Additional Ecotoxicological Remarks

No data available for this product.

13. Disposal considerations

Waste Disposal Method

Waste disposal should be in accordance with existing federal, state and local environmental control laws.

14. Transport information

Land transport (DOT)

Non-Regulated

Sea transport (IMDG)

Non-Regulated

Air transport (ICAO/IATA)

Non-Regulated

15. Regulatory information

United States Federal Regulations

OSHA Hazcom Standard Rating: Non-Hazardous

US. Toxic Substances Control Act: Excluded: Article.

US. EPA CERCLA Hazardous Substances (40 CFR 302):

Components

None

SARA Section 311/312 Hazard Categories:

Non-hazardous under Section 311/312

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A):

Components

None

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) - Supplier Notification Required:

Components

None

US. EPA Resource Conservation and Recovery Act (RCRA) Composite List of Hazardous Wastes and Appendix VIII Hazardous Constituents (40 CFR 261)

Under RCRA, it is the responsibility of the person who generates a solid waste, as defined in 40 CFR 261.2, to determine if that waste is a hazardous waste.

State Right-To-Know Information

The following chemicals are specifically listed by individual states; other product specific health and safety data in other sections of the MSDS may also be applicable for state requirements. For details on your regulatory requirements you should contact the appropriate agency in your state.

Massachusetts, New Jersey or Pennsylvania Right to Know Substance Lists:

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<u>Weight percent</u>	<u>Components</u>	<u>CAS-No.</u>
>=1%	Polyurethane Polyether Elastomer	9018-04-6
>=1%	Proprietary Non-Hazardous Ingredients	

California Prop. 65:

To the best of our knowledge, this product does not contain any of the listed chemicals, which the state of California has found to cause cancer, birth defects or other reproductive harm.

16. Other information

HMIS Rating

Health 0

Flammability 1

Physical Hazard 0

0=Minimal 1=Slight 2=Moderate 3=Serious 4=Severe

* = Chronic Health Hazard

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