

Title: MSDS for Invisalign Appliance Materials – EX15, EX30, and EX40		ECO Number: SJ003732
Doc Number: 2088	Rev: C	Last Print Date: 01/07/13

MATERIAL SAFETY DATA SHEET



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

1. CHEMICAL PRODUCT & COMPANY IDENTIFICATION

Product names:

- EX30 – Invisalign® Aligners
- EX40 – Vivera® and Invisalign® Retainers
- EX15 – Invisalign® Templates

2. COMPOSITION/ INFORMATION ON INGREDIENTS

- 2.1. Polyurethane from methylene diphenyl diisocyanate and 1, 6-hexanediol.
CAS# 137873-51-9
- 2.2. Additives

3. HAZARDS IDENTIFICATION

3.1. EMERGENCY OVERVIEW

- 3.1.1. This product consists primarily of high molecular weight polymers which are not expected to be hazardous.
- 3.1.2. Can burn in a fire creating dense, toxic smoke.
- 3.1.3. Molten plastic can cause severe burns.
- 3.1.4. Odorless.
- 3.1.5. No significant immediate hazards for emergency response are known.

3.2. POTENTIAL HEALTH EFFECTS (See Section 11 for toxicological data.)

- 3.2.1. EYE: Solid or dust may cause irritation or corneal injury due to mechanical action. Elevated temperatures may generate vapor levels sufficient to cause eye irritation.
- 3.2.2. SKIN: Essentially nonirritating to skin. Mechanical injury only. Molten material may burn skin. Skin absorption is unlikely due to physical properties.

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- 3.2.3. **INGESTION:** Single dose oral toxicity is considered to be extremely low. No hazards anticipated from swallowing small amounts incidental to normal handling operations.
- 3.3. **INHALATION:** Dust may cause irritation of the upper respiratory tract. At room temperature, Exposure to vapors is unlikely due to physical properties: normal-processing temperatures may generate vapors which may cause irritation if ventilation is inadequate.
- 3.4. **SYSTEMIC (OTHER TARGET ORGAN) Effects:** No specific data: however, repeated exposure to the unheated material are not anticipated to cause significant adverse effects. Processing fumes may cause eye and respiratory irritation upon repeated exposure.
- 3.5. **CANCER INFORMATION:** No relevant information found.
- 3.6. **TERATOLOGY (BIRTH DEFECTS):** No relevant information found.
- 3.7. **REPRODUCTIVE EFFECTS:** No relevant information found.
- 4. FIRST AID**
 - 4.1. **EYES:** Flush eyes with plenty of water.
 - 4.2. **SKIN:** Wash off the following water or shower.
 - 4.3. **INGESTION:** No adverse effects anticipated by this route of exposure incidental to proper industrial handling.
 - 4.4. **INHALATION:** Remove to fresh air if effects occur. Consult a physician.
 - 4.5. **NOTE TO PHYSICIAN:** If burn is present, treat as any thermal burn, after decontamination. No specific antidote. Supportive care. Treatment based on judgment if the physician in response to reactions of the patient.
- 5. FIRE FIGHTING MEASURES**
 - 5.1. **FLAMMABLE PROBERTIES**
 - 5.1.1. **FLASH POINT:** Not applicable
 - 5.1.2. **METHOD USED:** Not applicable
 - 5.2. **FLAMABLE LIMITS**
 - 5.2.1. **LFL:** Not applicable
 - 5.2.2. **UFL:** Not applicable

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5.3. **HAZARDOUS COMBUSTION PRODUCTS:** Under fire conditions polymers decompose. The smoke may contain polymer fragments of varying compositions in addition to unidentified toxic and/or irritating compounds. Hazardous combustion products may include and are not limited to Carbon monoxide and Carbon dioxide and trace amounts of aromatic hydrocarbons as hydrogen cyanide.

5.4. **OTHER FLAMABLE INFORMATION:** Dense smoke is emitted when burned without sufficient oxygen. Mechanical handling can cause formation of dusts. To reduce the potential for dust explosion, do not permit dust to accumulate.

5.5. **EXTINGUISHING MEDIA:** Water, Carbon dioxide or Dry chemical.

5.6. **FIRE FIGHTING INSTRUCTIONS:** Keep people away. Isolate fire area and deny unnecessary entry. Cool surroundings with water to localize fire zone. Hand held carbon dioxide or dry chemical extinguishers may be used for small fires. Soak thoroughly with water to cool and prevent re-ignition.

5.7. **PROTECTIVE EQUIPMENT FOR FIREFIGHTERS:** Wear positive-pressure-self-containing breathing apparatus (SCBA) and protective fire fighting clothing (includes fire fighting helmet, coat, pants, boots, and gloves). If protective equipment is not available or not used, fight fire from a protected location or safe distance.

6. ACCIDENTAL RELEASE MEASURES (See Section 15 for Regulatory Information)

6.1. **PROTECT PEOPLE:** Pellets or beads may present a slipping hazard.

6.2. **PROTECT THE ENVIRONMENT:** Spills should be collected to prevent contamination or Waterways. Material is heavier than water and had limited water solubility. It will collect on the lowest surface. See section 13 for more specific information.

6.3. **CLEANUP:** Sweep up.

7. HANDLING AND STORAGE

7.1. **HANDLING:** Good housekeeping and controlling of dusts are necessary for safe handling of product.

7.2. **STORAGE:** Store in a dry place.

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1. ENGINEERING CONTROLS: Good general ventilation should be sufficient for most conditions. Local exhaust ventilation may be necessary for some operations.
- 8.2. PERSONAL PROTECTIVE EQUIPMENT
- 8.3. EYE/FACE PROTECTION: Use safety glasses. If there is a potential for exposure to particles which could cause mechanical injury to the eye, wear chemical goggles. If vapor exposure causes eye discomfort, use a full-face respirator.
- 8.4. SKIN PROTECTION: No precautions other than clean body-covering clothing should be needed. Use gloves with insulation for thermal protection, when needed.
- 8.5. RESPIRATORY PROTECTION: For most conditions, no respiratory protection should be needed; however, if handling at elevated temperatures without sufficient ventilation, use an approved air-purifying respirator. In dusty atmospheres, use an approved dust respirator.
- 8.6. EXPOSURE GUIDELINE (S): None established

9. PHYSICAL AND CHEMICAL PROPERTIES

- 9.1. APPEARANCE: Clear to pale yellow pellets.
- 9.2. ODOR: Odorless.
- 9.3. BOILING POINT: Not applicable.
- 9.4. VAP. PRESS: Not applicable.
- 9.5. VAP. DENSITY: Not applicable.
- 9.6. SOL. IN WATER: Insoluble.
- 9.7. SP. GRAVITY: 1.1 – 1.2

10. STABILITY AND REACTIVITY

- 10.1. CHEMICAL STABILITY: Thermally stable at typical use temperatures.
- 10.2. CONDITIONS TO AVOID: Avoid temperatures above 500F (260°C).
- 10.3. INCOMPATIBILITY WITH OTHER MATERIALS: Non known
- 10.4. HAZARDOUS DECOMPOSITION PRODUCTS: Processing may release fumes, which may include polymer fragments and other decomposition products. Fumes can be irritating. At temperatures exceeding melt temperatures, polymer fragments can occur. Hazardous decomposition products may include and are not limited to aliphatic and aromatic compounds, carbon dioxide and trace amounts of hydrogen cyanide.
- 10.5. HAZARDOUS POLYMERIZATION: Will not occur.

11. TOXICOLOGICAL INFORMATION

- 11.1. ACUTE INGESTION: Single dose oral LD50 has not been determined.

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11.2. MUTAGENICITY (EFFECTS ON GENETIC MATERIAL): No relevant information found.

12. ECOLOGICAL INFORMATION**12.1. ENVIRONMENTAL FATE**

12.2. MOVEMENT & PARTITIONING: No bio-concentration is expected because of high molecular weight (MW > 1000). In the terrestrial environment, material is expected to remain in the soil. In the aquatic environment, material will sink and remain in the sediment.

12.3. DEGRADATION & PERSISTENCE: This water insoluble polymeric solid is expected to be essentially un-reactive in the environment over a period of many years. Surface photo degradation is expected with exposure to sunlight. No appreciable biodegradation is expected.

12.4. ECOTOXICITY: Not expected to be acutely toxic, but pellets, if ingested by waterfowl or aquatic life, may mechanically cause adverse effects.

13. DISPOSAL CONSIDERATIONS

13.1. DISPOSAL: DO NOT DUMP INTO ANY SEWERS, ON THE GROUND, OR INTO ANY BODY OF WATER. All disposal methods must be in compliance with all Federal, State/Provincial and local laws and regulations. Regulations may vary in different locations. Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

13.2. FOR UNUSED & UNCONTAMINATED PRODUCT, the preferred options include sending to a licensed, permitted: recycler, re-claimer, incinerator or other thermal destruction device, or landfill.

14. TRANSPORT INFORMATION

14.1. UNITED DOT INFORMATION: This product is not regulated by D.O.T. when shipped domestically by land.

14.2. CANADIAN TDG INFORMATION: This product is not regulated by TDG when shipped domestically by land.

15. REGULATORY INFORMATION (Not meant to be all inclusive—selected regulations represented)

15.1. NOTICE: The information herein is presented in good faith and believed to be accurate as of the effective date shown above. However, no warranty, express or implied is given. Regulatory requirements are subject to change and may differ from one location to another; it is the buyer's responsibility to ensure that its activities comply with federal, state or provincial, and local laws. The following

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specific information is made for the purpose of complying with numerous federal, state, or provincial, and local laws and regulations. See other sections for health and safety information.

15.2. U.S. REGULATIONS

15.2.1. SARA 313 INFORMATION: To the best of our knowledge, this product contains no chemical subject to SARA Title III Section 313 supplier notification requirements.

15.2.2. SARA HAZARD CATEGORY: This product has been reviewed according to the EPA “Hazard Categories” promulgated under Section 311 and 312 of the Superfund Amendment and Reauthorization Act of 1986 (SARA Title III) and is considered, under applicable definitions, to meet the following categories:

15.2.2.1. Not to have met any hazard category

15.2.3. TOXIC SUBSTANCES CONTROL ACT (TSCA):

15.2.3.1. All ingredients are on the TSCA Inventory or are not required to be listed on the TSCA inventory.

15.2.4. STATE RIGHT-TO-KNOW: This product is not known to contain any substances subject to the disclosure requirements of

15.2.4.1. New Jersey

15.2.4.2. Pennsylvania

15.2.5. OSHA HAZARD COMMUNICATION STANDARD:

15.2.5.1. This product is not a “Hazardous Chemical” as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

15.2.6. COMPREHENSIVE ENVIRONMENTAL RESPONSE

COMPENSATION AND LIABILITY ACT (CERCLA, OR SUPERFUND):

15.2.6.1. To the best of our knowledge, this product contains no chemical subject to reporting under CERCLA.

16. CANADIAN REGULATIONS

16.1. WHMIS INFORMATION: The Canadian Workplace Hazardous Materials Information System (WHMIS) Classification for the product is:

16.1.1. This product is not a “Controlled” Product: under WHMIS.