

Section 1. Identification

1.1 Product identifier

Product name: Zendura® TRAK
Other identifiers: None

1.2 Relevant identified uses of the substance and uses advised against

Recommended use: May be used as received, processed, or thermoformed to produce other articles, or as a component of other dental products.

Uses advised against: No information available

1.3 Supplier details:

Company name: Bay Materials
Address: 48450 Lakeview Blvd.
 Fremont, CA 94538
Telephone: +1-(650)-566-0800
 Email: complaints@baymaterials.com
 Website: www.baymaterials.com

1.4 Emergency telephone number:

Emergency Phone Number
 for Spill, Leak, Fire, Exposure, or Accident
 Call INFOTRAC Day or Night
NORTH AMERICA 1-800-535-5053
INTERNATIONAL 1-352-323-3500

Section 2. Hazard Identification

<p>Hazard Classification</p> <p>According to Regulation (EC) No. 1272/2008 [CLP] and Global Harmonized System (GHS) standards</p>	<p>Further information</p> <p>NFPA 704:</p> <div style="text-align: center;"> <p>Health: 1, Flammability: 1, Instability: 0, Special hazard: empty</p> </div>	<p>HMIS® IV:</p> <table border="1" style="width: 100%; text-align: center;"> <tr> <td style="background-color: #0000FF; color: white;">HEALTH</td> <td style="width: 20px;">/</td> <td style="width: 20px;">1</td> </tr> <tr> <td style="background-color: #FF0000; color: white;">FLAMMABILITY</td> <td></td> <td>1</td> </tr> <tr> <td style="background-color: #FFD700; color: black;">PHYSICAL HAZARD</td> <td></td> <td>0</td> </tr> </table> <p>HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "/" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.</p>	HEALTH	/	1	FLAMMABILITY		1	PHYSICAL HAZARD		0
HEALTH	/	1									
FLAMMABILITY		1									
PHYSICAL HAZARD		0									
<p>Label elements</p>	<p>The product does not require a hazard warning label in accordance with GHS criteria. Hazards not otherwise classified.</p>										

	No specific dangers known, if the regulations/notes for storage and handling are considered.
Signal word	Warning
Hazard statements	If fine particles are generated during further processing, handling or by other means, product may form combustible dust concentrations in air.
Precautionary Statement	P261: Avoid breathing dust/fume/gas/mist/vapors/spray. P280: Wear protective gloves
Labeling of special preparations (GHS)	Under thermoforming or processing conditions, wear personal protective equipment to prevent thermal burns. Use with local exhaust ventilation.
2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200	According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200 This product does not contain any components classified as hazardous under the referenced regulation.

Section 3. Composition / Information on Ingredients

Chemical name	CAS Number	Content (W/W)
Copolyester	Proprietary	100%

Section 4. First-Aid Measures

Primary Routes of Exposure	Eyes, skin, mouth or inhalation
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4.1 Description of first aid measures

- If inhaled:** Remove the affected individual into fresh air. Treat symptomatically. If symptoms persist, call a physician
- If on skin:** Skin contact with hot molten substance/product may cause thermal burns. Cool skin rapidly with cold water after contact with molten materials. Do not peel solidified product off the skin. Burns must be treated by a physician.
- If in eyes:** In case of contact with the eyes, rinse immediately with plenty of water and seek medical attention.
- If swallowed:** Seek medical advice.
- Most important symptoms and effects,** See Section 11
Acute: Contact with heated material can cause thermal burns. Causes a

both acute and delayed

slipping hazard if spilled.
Vapors released from thermal decomposition may cause eye irritation with symptoms of burning and tearing, as well as respiratory tract irritation

Hazards:

Contact with molten substance/product may cause severe burns to skin and eyes

Treatment:

Symptomatic

Note to physician

Treatment: Treat according to symptoms (decontamination, vital functions).
No known specific antidote. Burns should be treated as thermal burns.

Section 5. Fire-Fighting Measures

5.1	Extinguishing media	Suitable extinguishing media	Water, Dry powder, Carbon dioxide
		Unsuitable Extinguishing Media:	High Pressure Water Streams may scatter and spread fire.
		Special hazards arising from the substance or mixture	Hazards during firefighting: No particular hazards known.
5.2	Advice for fire-fighters	Protective equipment for firefighting	Firefighters should be equipped with self-contained breathing apparatus to protect against potentially toxic and irritating fumes and turn-out gear.
5.3	Unusual Fire/Explosion Hazards	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.	
5.4	Further information	Minimize dust generation and accumulation	

Section 6. Accidental release measures

6.1	Personal precautions, protective equipment and emergency procedures	Wear appropriate personal protective equipment. Local authorities should be advised if significant spillages cannot be contained.
6.2	Environmental precautions	Avoid release to the environment

6.3	Methods and material for containment and cleaning up	Spills should be contained and placed in suitable containers for disposal.
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Section 7. Handling and Storage

7.1	Precautions for safe handling	Provide suitable exhaust ventilation when thermoforming or trimming.
7.2	Protection against fire and explosion:	No explosion proofing necessary. 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. Material is hygroscopic and may absorb small amounts of atmospheric moisture. Minimize dust generation and accumulation. Routine housekeeping should be instituted to ensure that dust does not accumulate on surfaces. Solid particulate can generate electrical charging during operations such as unloading from containers and pneumatic transfer. Provide adequate precautions, such as electrical grounding and bonding, where conductive equipment is involved.
7.3	Conditions for safe storage	Keep tightly closed. Keep container tightly closed

Section 8. Exposure Controls/Personal Protection

8.1 Control parameters

8.1.2 Occupational Exposure

Contains no substances with occupational exposure limit values.

Advice on system design **Provide local exhaust ventilation to control dust.**

Industrial Hygiene/Ventilation Measures	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.
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Personal protective equipment

Respiratory protection:	Wear a NIOSH-certified (or equivalent) organic vapor/particulate respirator as needed. In the absence of sufficient general dilution or local exhaust ventilation, a NIOSH approved air-supplied respirator may be needed during high temperature processing, procedures that create particulate matter, or when thermal decomposition is suspected.
Hand protection:	Wear gloves to prevent contact during mechanical processing and/or hot melt conditions. Ensure gloves remain in good condition during use and replace if any deterioration is observed.
Eye protection:	Wear splash goggles or a face shield to protect from hot molten substance/product.
General safety and hygiene measures:	Wear protective clothing to prevent contact during mechanical processing and/or hot melt conditions. Avoid inhalation of dust. When using, do not eat, drink or smoke. Hands and/or face should be washed before breaks and at the end of the shift. At the end of the shift the skin should be cleaned and skin-care agents applied. Educate and train employees in the safe use and handling of this product.

Section 9. Physical and Chemical Properties
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9.1 Information on basic physical and chemical properties

9.1.1	Form:	Sheet	
9.1.2	Odor:	mild	
9.1.3	Colour:	colorless	
9.1.4	pH value:		Not applicable
9.1.5	Melting point:		Not determined
9.1.6	Boiling point:		Not determined
9.1.7	Flammability:	not flammable	
9.1.8	Lower explosion limit:		For solids not relevant for classification and labelling.
9.1.9	Upper explosion limit:		For solids not relevant for classification and labelling
9.1.10	Autoignition:		Not applicable
9.1.11	Vapor pressure:		Not applicable.
9.1.12	Relative density:	>1	
9.1.13	Auto-ignition Temperature:		Not determined

9.1.14	Decomposition Temperature:	Decomposition begins at 230°C
9.1.15	Dynamic Viscosity	No Data Available
9.1.16	Kinematic Viscosity:	No Data Available

Section 10. Stability and Reactivity

10.1	Reactivity	None reasonably foreseeable
10.2	Corrosion to metals	No corrosive effect on metal.
10.3	Oxidizing properties	Not an oxidizer
10.4	Chemical stability	The product is stable if stored and handled as prescribed/indicated
10.5	Possibility of hazardous reactions	The product is chemically stable. No hazardous reactions if stored and handled as prescribed/indicated.
10.6	Conditions to avoid	No conditions known that should be avoided. Generation of dust clouds and dust accumulation
10.7	Incompatible materials	Strong oxidizing agents
10.8	Hazardous decomposition products	Carbon monoxide Carbon dioxide

Section 11. Toxicological information

Acute toxicity
Not classified based on available information.

Acute oral toxicity	Not classified based on available information
Acute inhalation toxicity	Remarks: No data available
Acute dermal toxicity	Not classified based on available information
Skin corrosion/irritation	Not classified based on available information.
Serious eye damage/eye irritation	Not classified based on available information.

Respiratory or skin sensitization	Not classified based on available information
Germ cell mutagenicity	Not classified based on available information.
Carcinogenicity	Not classified based on available information.

11.1 Information on likely routes of exposure

Routes of entry for solids and liquids are ingestion and inhalation but may include eye or skin contact. Routes of entry for gases include inhalation and eye contact.

ACUTE TOXICITY	
Acute Toxicity/Effects	Contact with heated material can cause thermal burns., Causes a slipping hazard if spilled
ASSESSMENT OF OTHER ACUTE EFFECTS	
Assessment of STOT single exposure:	Based on the available information there is no specific target organ toxicity to be expected after a single exposure
IRRITATION / CORROSION	
Assessment of irritating effects:	Not irritating to the eyes. Not irritating to the skin.
Assessment of sensitization:	The chemical structure does not suggest a sensitizing effect. Biocompatibility testing per ISO 10993 did not show sensitization
Aspiration Hazard	No aspiration hazard expected.
11.2 INFORMATION ON CHRONIC TOXICITY / EFFECTS	
Repeated dose toxicity	Assessment of repeated dose toxicity: No known chronic effects. Repeated exposure to the substance by dermal administration leads to effects similar to those found after single exposure. Repeated exposure to the substance by inhalative administration leads to effects similar to those found after single exposure. Repeated exposure to the substance by oral administration leads to effects similar to those found after single exposure
GENETIC TOXICITY	
Assessment of mutagenicity	The chemical structure does not suggest a specific alert for such an effect.
CARCINOGENICITY	
Assessment of	The chemical structure does not suggest a specific alert for such an

carcinogenicity:	effect.	
	No carcinogenic substances as defined by IARC, NTP and/or OSHA	
	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.
REPRODUCTIVE TOXICITY		
Assessment of reproduction toxicity:	The chemical structure does not suggest a specific alert for such an effect.	
Teratogenicity	Assessment of teratogenicity: The chemical structure does not suggest a specific alert for such an effect	
Endocrine Disruptor Information	Bisphenol A is not used in the manufacture or formulation of this product	
Other Information	The product has been tested and has passed biocompatibility assesments per the requirements of ISO 10993	
Symptoms of Exposure	No significant reaction of the human body to the product known	

Section 12. Ecological Information

12.1 ECOTOXICITY

Ecotoxicity **No data available**

12.2 Persistence and degradability No data available

12.3 Bioaccumulative potential No data available

12.4 Mobility in soil No data available

Section 13. Disposal considerations

Dispose of in accordance with local regulations.

Section 14. Transport Information

Land transport USDOT	Not regulated.
Sea transport IMDG	Not regulated.
Air transport IATA/ICAO	Not regulated.
Code of Emergency Measure:	Not regulated.
Domestic Standard:	In compliance with domestic law.
Environmental hazards:	Not regulated.
Special precautions for user:	No special precautions.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:	None known.

International Regulations

IATA-DGR	Not regulated as a dangerous good
IMDG-Code	Not regulated as a dangerous good
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable for product as supplied
Domestic regulation 49 CFR	Not regulated as a dangerous good

Section 15. Regulatory Information

15.1 Safety, health, and environmental regulations/legislation specific for the product:

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards: Combustible dust

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

California Prop. 65: This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

The ingredients of this product are reported in the following inventories:

TCSI: On the inventory, or in compliance with the inventory
TSCA: All substances listed as active on the TSCA inventory
AICS: On the inventory, or in compliance with the inventory
DSL: All components of this product are on the Canadian DSL
ENCS: On the inventory, or in compliance with the inventory
ISHL: On the inventory, or in compliance with the inventory
KECI: On the inventory, or in compliance with the inventory
PICCS: Not listed
IECSC: On the inventory, or in compliance with the inventory
NZIoC: On the inventory, or in compliance with the inventory
COSHH: Not listed

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

Section 16. Other Information

Zendura® TRAK Thermoformable sheet is a trademark of Bay Materials, LLC

Full text of other abbreviations

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 Standardization; 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 Organization 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;

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