PRODUCT NAME: Zendura® A or Zendura®

PRODUCT NUMBERS: 9155, 9156, 9157, 9162, 9163, 9164 EFFECTIVE DATE: 10/29/2013

MATERIAL SAFETY DATA SHEET

PRODUCT NAME(s): Zendura® A or Zendura®; Dental Retainer Sheet; Thermoform Sheet Materials

CHEMICAL CLASS: Polyurethane Resin

CAS NUMBER: 137873-51-9

The components listed below are identified as hazardous chemicals under criteria of the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Name None	CAS Number	N.A.	<u>Approx. %</u>
Significant Nonhazardous Ingredien	ts		
Name Polyurethane	CAS Number	137873-51-9	<u>Approx. %</u> >98
None of the ingredients present at ec	ual to or greate	r than 0.1% of this pro	duct are listed by

None of the ingredients present at equal to or greater than 0.1% of this product are listed by OSHA, NTP or IARC as suspect carcinogens.

HAZARD IDENTIFICATION

EMERGENCY OVERVIEW

Clear to slightly violet plastic sheet. No significant immediate hazards for emergency response are known.

UNUSUAL FIRE AND EXPLOSION HAZARDS Products of combustion are toxic. During a fire this product may produce vapors and/or fumes that may cause eye, skin and respiratory tract irritation. Exposure may aggravate existing conditions like bronchial asthma.

POTENTIAL HEALTH EFFECTS FOR ROUTE OF ENTRY:

SKIN CONTACT: Frequent or prolonged contact may irritate the skin and cause a skin rash (dermatitis). EYE CONTACT: Dust generated from this product may irritate the eyes.

INGESTION: Not a likely source of exposure. This product has a very low solubility in body fluids and has low acute toxicity.

INHALATION: Dust generated from this product may be irritating to the respiratory tract.

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CHRONIC HEALTH EFFECTS: No long tern effects are expected from the product as it is received. Exposure to fumes and dusts generated during processing may result in chronic effects.

FIRST AID MEASURES

SKIN CONTACT: Wash thoroughly with soap and water.

EYE CONTACT: Holding eyelids apart, immediately flush eyes with large amounts of water for at least 15 minutes..

INHALATION: No specific treatment is necessary since this product is not likely to be hazardous by inhalation. If exposed to excessive levels of dusts or fumes, remove to fresh air and seek medical attention if cough or other symptoms develop.

INGESTION: For excessive ingestion, drink water or milk and call a physician. Never give anything to an unconscious person.

FIRE FIGHTING MEASURES

FLASH POINT: N.A.

LOWER FLAMMABILITY : Not established

UPPER FLAMMABILITY: Not established

METHOD: N.A.

EXTINGUISHING MEDIA: CO₂, foam, or dry chemical

SPECIAL FIRE FIGHTING PROCEDURES: Wear NIOSH/MSHA self-contained breathing apparatus (SCBA)equipped with a full face piece and operated in a pressure-demand mode or other positive-pressure mode, and protective clothing.

UNUSUAL FIRE AND EXPLOSION HAZARDS: Products of combustion are toxic.

ACCIDENTAL RELEASE

SPILL CLEAN UP: Prevent additional discharge. Vacuum or sweep up material and place into a disposal container, or reuse if possible. Avoid dust generation.

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HANDLING/STORAGE

HANDLING AND STORAGE PRECAUTIONS: Minimize dust generation and accumulation. Wash hands before eating. Store in closed containers away from heat and moisture in a ventilated area. Keep tightly closed when not in use.

EXPSOURE CONTROLS/PERSONAL PROTECTION

EYE PROTECTION: Safety glasses with side shields (or goggles) are recommended for any type of chemical handling.

SKIN PROTECTION: When material is heated wear gloves and protective clothing to protect against thermal burns.

RESPIRATORY PROTECTION: If thermal degradation is possible, use of a NIOSH/MSHAapproved air purifying respirator with organic vapor/acid gas/HEPA combination cartridge or air-supplied respirator is recommended in the absence of environmental controls.

VENTILATION AND ENGINEERING CONTROLS: Ventilation should be sufficient to remove any dusts and fumes generated during processing of this product.

PHYSICAL PROPERTIES

APPEARANCE:	Rigid Sheet	ODOR:	N.A.
PHYSICAL STATE	Solid	pH	N.A.
VAPOR PRESSURE:	N.A.	BOILING POINT:	N.A.
MELTING POINT:	Not Determined	SOLUBILITY IN WATER:	Negligible
SPECIFIC GRAVITY:	1.203	VOC:	No Data
VOC less water and exempt	solvent: No da	ta	

STABILITY/REACTIVITY

STABILITY AT ROOM TEMP.:StableCONDITIONS TO AVOID:Do not heat above combustion temperature 230°C.INCOMPATIBILITY:NoneHAZARDOUS DECOMPOSITION PRODUCTS:Will emit carbon monoxide, carbon dioxideand organic fumes if heated to combustion temperature.HAZARDOUS POLYMERIZATION:Will not occurWill not occur

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TOXICOLOGICAL INFORMATION

This sheet product has undergone biocompatibility testing in compliance with U.S. Pharmacopeia XXII, Part 88, Class VI guidelines.

Post-thermoformed sheets fashioned into finished devices have been tested in compliance with ISO 10993 biocompatibility standards.

ECOLOGICAL/DISPOSAL INFORMATION

DISPOSAL: Incinerate or landfill waste in a properly permitted facility in accordance with federal, state, and local regulations.

TRANSPORT INFORMATION

DOT Shipping Name:	Not regulated
DOT Label:	Not regulated

REGULATORY INFORMATION

INVENTORY STATUS

TSCA: This product is a mixture of ingredients, all of which are listed on the TSCA inventory. EINECS DSL

SARA Title III Section 311 Ratings Fire Hazard: N Reactive Hazard: N Release of Pressure: N Acute Health hazard: N Chronic Health Hazard: N

Proposition 65 Chemicals: N

There are no chemicals in this product at a concentration of 0.1% or greater listed as known or anticipated carcinogens by IARC, NTP OSHA or ACGIH.

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Prepared by: Aimee Luthringer Date: 10/28/2013

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