DENTSPLY International

DENTSPLY PROSTHETICS

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: 25 June 1997 Document Number: 097 Date Revised: 22 April 2015 Revision Number: 4

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled): Triad® VLC Custom Tray Material

Part/Item Number: 89783, 95746, 95752

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use: Resin used in removable dental appliances

Restrictions on Use: For Professional Use Only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name: DENTSPLY Prosthetics
Manufacturer/Supplier Address: 570 West College Ave.

York, PA 17401

Manufacturer/Supplier Telephone Number: 717-845-7511 (Product Information)

Email address: Prosthetics_MSDS@Dentsply.com

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number: 800-424-9300 Chemtrec

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:		
Health	Environmental	Physical
Eye Irritant Category 2A (H319) Skin Irritant Category 2 (H315) Specific Target Organ Toxicity - Single Exposure Category 3 (Respiratory Irritant) (H335) Skin Sensitization Category 1 (H317)	Not Hazardous	Not Hazardous

EU Classification: Irritant (Xi), R36/37/38, R43

2.2 Label Elements:



Signal Word: Warning

Contains: Sodium Aluminum Silicate and Polyester Urethane Acrylate

Hazard Phrases	Precautionary Phrases
H315 Causes skin irritation.	P261 Avoid breathing mist, vapors or spray.
H317 May cause an allergic skin reaction.	P264 Wash thoroughly after handling.
H319 Causes serious eye irritation.	P271 Use only outdoors or in a well-ventilated area.
H335 May cause respiratory irritation.	P280 Wear protective gloves and eye protection.
	P305+P351+P338 IF IN EYES: Rinse cautiously with
	water for several minutes. Remove contact lenses, if
	present and easy to do. Continue rinsing.
	P337+P313 If eye irritation persists: Get medical attention.
	P302+P352 IF ON SKIN: Wash with plenty of soap and
	water.
	P333+P313 If skin irritation or rash occurs: Get medical
	attention.
	P362+P364 Take off contaminated clothing and wash
	before reuse.
	P304+P340: IF INHALED: Remove person to fresh air and
	keep comfortable for breathing.
	P312 Call a POISON CENTER or doctor if you feel unwell.
	P403+P233 Store in a well-ventilated place. Keep
	container tightly closed.
	P405 Store locked up.
	P501 Dispose of contents and container in accordance with
	local and national regulations.

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Sodium Aluminum Silicate	68476-25-5		Xi, R36/37	30-60
			Eye Irrit 2 (H319),	
			STOT SE 3 (H335)	
Polyester Urethane Acrylate	71833-41-5	Not listed	Xi, R36/38, R43	20-30
			Skin Irrit 2 (H315),	
			Eye Irrit 2 (H319),	
			Skin Sens 1 (H317)	
1, 6 Hexanediol Dimethacrylate	6606-59-3	229-551-7	Xi R36/37/38	1-5
			Skin Irrit 2 (H315),	
			Eye Irrit 2 (H319),	
			STOT SE 3 (H335)	
Non-Silaned Fumed Silica	7631-86-9	231-545-4	Not Applicable	1-5

Dimethylaminoethyl Methacrylate	2867-47-2	220-688-8	C, Xn, Xi R21/22, R43	<1
			Acute Tox. 4 (H302, H312),	
			Skin Corr 1B (H314),	
			Eye Dam 1 (H318),	
			Skin Sens 1 (H317)	

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS and EU Classifications.

4. FIRST AID MEASURES

4.1 Description	on of First Aid Measures:	
Eye	Flush eyes with large quantities of water several minutes, while holding the eyelids apart. Get medical attention if irritation persists.	
Skin	Remove clothing. Wash skin thoroughly with soap and water for several minutes. Get medical attention if irritation or rash develops. Launder contaminated clothing before re-use.	
Inhalation	Remove victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. Get medical attention if irritation develops or breathing is difficult.	
Ingestion	Do not induce vomiting. If conscious, wash mouth out with water. Never give anything by mouth to an unconscious or convulsing person. Get medical attention if you feel unwell.	
4.2 Most Imp	ortant Symptoms and Effects, Both Acute and Delayed:	
May cause serious eye irritation. May cause skin irritation and sensitization. Inhalation of vapors or mist may cause respiratory irritation and central nervous system effects such as headache, dizziness, drowsiness, nausea and unconsciousness.		
4.3 Indication	of Any Immediate Medical Attention and Special Treatment Needed:	

Immediate medical attention is required for eye contact, inhalation and ingestion.

Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	Use water fog, foam, and carbon dioxide.				
5.2 Special Hazards Arising	5.2 Special Hazards Arising from the Substance or Mixture:				
	ht may cause a polymerizing retion may yield oxides of carbon		n may release acrid smoke or		
5.3 Advice for Fire-Fighters	:				
Fire Fighting Procedures:	Cool exposed intact containers	s with water spray.			
Precautions for Fire Fighters:	Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. Do not enter fire area without proper protection. Contain water used in firefighting from entering sewers or natural waterways.				
	Recommended Protective E	quipment for Fire Fighters:			
EYES/FACE	HANDS RESPIRATORY THERMAL				
E y					

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Evacuate spill area and keep unprotected personnel away. Ventilate area. Wear appropriate protective clothing as described in Section 8. Avoid contact with skin, eyes or clothing.

Recommended Personal Protective Equipment for Containment and Clean-up:					
EYES/FACE	HANDS	RESPIRATORY			







SKIN

6.2 Environmental Precautions:

Avoid releases to the environment. Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Spread the paste to maximize the surface area. Once the material is hard, pick up and place into a container for disposal. Spill and release reporting requirements vary. Consult local authorities regarding requirements.

6.4 Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handing:

Avoid contact with the eyes, skin and clothing. Wear protective clothing and equipment as described in Section 8. Use with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use.

Empty containers retain product residues can be hazardous. Follow all MSDS precautions when handling empty containers.

- **7.2 Conditions for Safe Storage, Including Any Incompatibilities:** Store in a tightly closed container in a cool, well ventilated location away from incompatible materials. Do not store near high temperatures or ignition sources. Prevent contact with moisture. Refrigeration prolongs shelf life. Store away from food or beverages.
- **7.3 Specific End Use (s):** For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:		
Occupational Exposure Limits:		
Sodium Aluminum Silicate	United States	None Established

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	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Polyester Urethane Acrylate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
1, 6 Hexanediol Dimethacrylate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Non-Silaned Fumed Silica	United States	80 mg/m³ TWA OSHA PEL % SiO ₂
	Germany	4 mg/m ³ TWA DFG MAK (inhalable)
	United Kingdom	6 mg/m³ TWA UK WEL (inhalable aerosol), 2.4 mg/m³ TWA (respirable aerosol)
	European Union	None Established
Dimethylaminoethyl Methacrylate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
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Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits.

Individual Protection Measures (PPE):

Specific Eye/face Protection: Chemical safety goggles should be worn where splashing is possible.

Specific Skin Protection: Wear impervious gloves such as butyl rubber or neoprene if needed to avoid skin contact.

Specific Respiratory Protection: None should be needed for normal use. If the exposure limits are exceeded an approved respirator with ammonia cartridges or supplied air respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice.

Specific Thermal Hazards: None required.

Recommended Personal Protective Equipment			
EYES/FACE	HANDS	RESPIRATORY	SKIN

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Blue paste	Explosive limits:	LEL: Not available UEL: Not available
Odor:	Mild ester odor	Vapor pressure (mmHg):	<1
Odor threshold:	Not determined	Vapor density:	Not applicable
рН:	Not available	Relative density:	1.6
Melting/freezing point:	Not available	Solubility:	Completely miscible
Initial boiling point and range:	Not available	Partition coefficient: n-octanol/water:	Not available
Flash point:	Not flammable	Auto-ignition temperature:	Not applicable
Evaporation rate:	Not available	Decomposition temperature:	Not determined
Flammability:	Not flammable	Viscosity:	Not applicable
Explosive Properties:	Not explosive	Oxidizing Properties:	Not oxodizing

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: Non-reactive

10.2 Chemical Stability: Stable

10.3 Possibility of Hazardous Reactions: Polymerizes to form hard plastic in 2 hours at 100°C (212°F) with low exotherm.

10.4 Conditions to Avoid: Avoid high temperatures and direct sunlight.

10.5 Incompatible materials: Avoid oxidizing agents, reducing agents, tertiary amines, heavy metals, peroxides, free radical initiators

10.6 Hazardous Decomposition Products: Decomposition may release oxides of carbon and methylmethacrylate.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: May cause serious irritation. Vapors may cause irritation with redness, burning and tearing.

Skin: May cause irritation. Prolonged exposure may cause dermatitis. May cause sensitization.

<u>Ingestion:</u> Ingestion may cause irritation of the mucous membranes, esophagus and stomach.

<u>Inhalation:</u> Inhalation of vapors or mists may cause moderate to severe irritation of mucous membrane and upper respiratory tract with coughing, sneezing and watering of the eyes.

Chronic Health Effects: None expected under normal use.

Irritation: Product is irritating to eyes and skin.

Corrosivity: Not a corrosive

Sensitization: This product is a skin sensitizer.

<u>Carcinogenicity:</u> None of the components of this product at 0.1% or greater are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.

Mutagenicity: No data available.

Medical Conditions Aggravated by Exposure:

Individuals with pre-existing skin disorders may be at increased risk from exposure.

Acute Toxicity Data:

Sodium Aluminum Silicate

Polyester Urethane Acrylate

1, 6 Hexanediol Dimethacrylate

Non-Silaned Fumed Silica: Oral rat LD50 > 5000 mg/kg, inhalation rat LC50 > 0.69 mg/L, dermal rabbit LD50 > 2000 mg/kg

Dimethylaminoethyl Methacrylate: Oral rat LD50 > 2000 mg/kg, dermal rat LD50 > 2000 mg/kg

Reproductive Toxicity Data: No data available.

Specific Target Organ Toxicity (STOT):

Single Exposure: No data available

Repeated Exposure: No data available

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Dimethylaminoethyl Methacrylate: Oryzias latipes LC50: 19.1 mg/L

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: Not required

12.6 Other Adverse Effects: None known

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Regulations: Dispose in accordance with all national and local regulations.

Properties (Physical/Chemical) Affecting Disposal: Empty containers retain product residues and can be hazardous.

Follow all SDS precautions when handling empty containers.

Waste Treatment Recommendations: Treat in accordance with national and local regulations.

14. TRANSPORT INFORMATION

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
DOT	None	Not Regulated	None	None	None
ADR/RID	None	Not Regulated	None	None	None
IMDG	None	Not Regulated	None	None	None
IATA/ICAO	None	Not Regulated	None	None	None

14.6 Special Precautions for User: Not applicable.

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA This product is not subject to CERCLA reporting requirements many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

Toxic Substances Control Act (TSCA): All of the components of this product are listed on the TSCA inventory.

Clean Water Act (CWA): This material is not regulated under the Clean Water Act.

Clean Air Act (CAA): This material is not regulated under the Clean Air Act.

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories:

Immediate Hazard:	Yes	Pressure Hazard:	No
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Delayed Hazard:	No	Reactivity Hazard:	No
Fire Hazard:	No		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
None		

State Regulations

California: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity:

Components	C.A.S. #	WT %
Titanium Dioxide	13463-67-7	<0.01

International Regulations

International Regulations

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

European Inventory of Existing Chemicals (EINECS): This product is a medical device and not subject to chemical notification requirements.

EU REACH: This product is a medical device and not subject to chemical notification requirements.

Australian Inventory of Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Japanese Existing and New Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a medical device and not subject to chemical notification requirements.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION			
HMIS Hazard Rating: Health – 2 Flammability – 1	Physical Hazard– 0		

Full text of Classification abbreviations used in Section 2 and 3:

C Corrosive

Xn Harmful

Xi Irritant

R34 Causes burns.

R36/37/38 Irritating to eyes, respiratory system and skin.

R36/38 Irritating to eyes and skin

R36/37 Irritating to eyes and respiratory system

R43 May cause sensitization by skin contact

Skin Sens 1 Skin Sensitizer Category 1

Acute Tox 4 Acute Toxicity Category 4

Eve Irrit. 2A Eye Irritant Category 2A

Skin Corr. 1B Skin Corrosion Category 1B

Skin Irrit. 2 Skin Irritant Category 2

STOT SE 3 Specific Target Organ Toxicity – Single Exposure Category 3

Eye Dam 1 Eye Damage Category 1

H302 Harmful if swallowed

H312 Harmful in contact with skin

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction

H318 May cause serious eye damage

H319 Causes serious eye irritation.

H335 May cause respiratory irritation

Supersedes: 27 February 2015

Revision Summary: Updated format.

Revision date: 22 April 2015

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau,

ESIS, Country websites for occupational exposure limits.