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
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Revision Number: 8

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

1.1 Product Identifier:

Trade Name (as labeled): **Triad® DuaLine® Dual-Cure Reline Material**

Part/Item Number: **905530, 905537**

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
Skin Sensitization Category 1 (H317)	Aquatic Chronic Toxicity Category 2 (H411)	Not Hazardous

EU Classification: Irritant (Xi) R43

2.2 Label Elements:

Signal Word: Warning

Contains: Urethane Dimethacrylate

Hazard Phrases	Precautionary Phrases
H317 May cause an allergic skin reaction.	P261 Avoid breathing dust or fume. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves. P302+P352 IF ON SKIN: Wash with plenty of soap and water. P333+P313 If skin irritation or rash occurs: Get medical attention. P363 Wash contaminated clothing before reuse. 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 %
Urethane Dimethacrylate	72869-86-4	276-957-5	Xi, N R43, R51/53 Skin Sens. 1, H317 Aquatic Acute 2, H401 Aquatic Chronic 2, H411	50-60
Amorphous Precipitated Silica	112945-52-5	231-545-4	Not Applicable	<5
Benzoyl Peroxide	94-36-0	202-327-6	E, O, Xi, N R3, R7, R36, R43, R50/53 Org. Perox. Type B, H241 Eye Irrit. 2A, H319 Skin Sens. 1, H317 Aquatic Acute 1, H400	<1
Oxybenzone	131-57-7	205-031-5	N R50/53 Aquatic Acute 1, H400 Aquatic Chronic 2, H411	0-0.5

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 of First Aid Measures:	
Eye	Rinse thoroughly with water, while holding the eye lids open to be sure the material is washed out. Get medical attention if irritation occurs and persists.
Skin	Remove clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation or rash develops. Launder contaminated clothing before re-use.
Inhalation	If irritation develops, remove to fresh air. Get medical attention if symptoms persist.
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 Important Symptoms and Effects, Both Acute and Delayed:
May cause eye and skin irritation. Prolonged or repeated contact may cause allergic skin reaction (sensitization). Individuals with sensitivity to methacrylates may develop an allergic reaction when exposed to this product.
4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:
Immediate medical attention should not be required.
Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	Use water fog, foam, carbon dioxide, water spray or dry chemical.
5.2 Special Hazards Arising from the Substance or Mixture:	
High temperatures and sunlight may cause a polymerizing reaction to occur. Decomposition may release acrid smoke or fumes, carbon oxides, and methyl methacrylate.	
5.3 Advice for Fire-Fighters:	
Fire Fighting Procedures:	Cool fire exposed containers and structures with water.
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 Equipment for Fire Fighters:			
EYES/FACE	**HANDS**	**RESPIRATORY**	**THERMAL**
			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:			
Avoid contact with skin, eyes or clothing. Avoid breathing dust or fumes. Wear appropriate protective clothing as described in Section 8.			
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:
Exposure to sunlight or artificial light will cause the paste to polymerize. Spread the paste to maximize the surface area. Once the material is hard, pick up and place into a container for disposal.
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. Avoid breathing dust or fumes. 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. Do not reuse containers. Empty containers retain product residues and can be hazardous. Follow all SDS 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:		
Urethane Dimethacrylate (as PNOC)	United States	5 mg/m^3 (Respirable fraction), 15 mg/m^3 (total dust) TWA OSHA PEL
	Germany	4 mg/m^3 TWA DFG MAK (Inhalable) (as dust, general threshold limit value)
	United Kingdom	None Established
	European Union	None Established

Amorphous Precipitated Silica	United States	20 mppcf TWA OSHA PEL
	Germany	4 mg/m^3 TWA DFG MAK (Inhalable)
	United Kingdom	6 mg/m^3 (Inhalable), 2.4 mg/m^3 (respirable) TWA UK WEL
	European Union	None Established

Benzoyl Peroxide	United States	5 mg/m^3 TWA ACGIH TLV 5 mg/m^3 TWA OSHA PEL
	Germany	5 mg/m^3 TWA (Inhalable), 5 mg/m^3 STEL (Inhalable) DFG MAK
	United Kingdom	5 mg/m^3 TWA UK WEL
	European Union	Belgium: 5 mg/m^3 TWA
Oxybenzone (as PNOC)	United States	5 mg/m^3 (Respirable fraction), 15 mg/m^3 (total dust) TWA OSHA PEL
	Germany	4 mg/m^3 TWA DFG MAK (Inhalable) (as dust, general threshold limit value)
	United Kingdom	None Established
	European Union	None Established
*****PNOC exposure limits only apply if dust is generated.		
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 or when grinding polymerized (cured) materials.

Individual Protection Measures (PPE):

Specific Eye/face Protection: Chemical safety glasses or goggles recommended.
Specific Skin Protection: Wear impervious gloves such as rubber to prevent skin contact. Consult glove supplier for thickness and breakthrough times.
Specific Respiratory Protection: None should be needed for normal use. If the product is heated, grinded, or ventilation is inadequate, an approved respirator with dust/mist 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:	Two pink, paste components in the uncured state. Pink, hard plastic when cured by mixing.	**Explosive limits:**	**LEL:** Not applicable **UEL:** Not applicable
Odor:	Characteristic odor	**Vapor pressure (mmHg):**	<1

Odor threshold:	Not applicable	**Vapor density:**	Not applicable
pH:	Not applicable	**Relative density:**	1.14
Melting/freezing point:	<-40°F (<-40°C)	**Solubility(ies):**	Negligible
Initial boiling point and boiling range:	Not applicable (polymerizes)	**Partition coefficient: n-octanol/water:**	Not applicable
Flash point:	Not applicable	**Auto-ignition temperature:**	Not applicable
Evaporation rate:	Not available	**Decomposition temperature:**	Not available
Flammability (solid, gas):	Not flammable	**Viscosity:**	Not available
Explosive Properties:	Non-Explosive	**Oxidizing Properties:**	None

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: Polymerization can occur.

10.2 Chemical Stability: Unstable if heated. Polymerizes to form a hard plastic in 6 hours at 60°C (140°F) with low exotherm.

10.3 Possibility of Hazardous Reactions: Polymerization will occur at elevated temperatures above 60°C (140°F).

10.4 Conditions to Avoid: Avoid excessive heat, flames, ignition sources and direct sunlight.

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

10.6 Hazardous Decomposition Products: Thermal decomposition may release acrid smoke or fumes, carbon oxides, and methyl methacrylate.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:
Eyes: May cause irritation with redness and tearing.
Skin: May cause irritation, redness, rash and swelling. May cause allergic skin reaction (sensitization).
Ingestion: None expected under normal use conditions.
Inhalation: None expected under normal use. Inhalation of dust from grinding plastic may cause respiratory irritation.

Chronic Health Effects: None expected under normal use.

Irritation: Urethane Dimethacrylate: Not irritating to rabbit skin and eyes. Benzoyl Peroxide: Not irritating to rabbit skin and was moderately irritating to rabbit eyes after 24 hours.

Corrosivity: This product is not classified as corrosive.

Sensitization: Urethane Dimethacrylate: Sensitizing in Mouse local lymphnode assay (LLNA). Benzoyl Peroxide: Benzoyl peroxide was found to be sensitizing in a mouse local lymphnode assay (LLNA). Individuals with sensitivity to methacrylates may develop an allergic reaction.

Carcinogenicity: 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. This product is not expected to cause mutagenic activity.

Medical Conditions Aggravated by Exposure:
Individuals with pre-existing skin and respiratory disorders may be at increased risk from exposure.

Acute Toxicity Data:

Urethane Dimethacrylate: Oral rat LD50->5000 mg/kg

Amorphous Precipitated Silica: Oral rat LD50- >10,000 mg/kg, Inhalation rat LC50- >0.139 mg/L/4h (highest concentration – no deaths), Skin rabbit LD50- >5000 mg/kg

Benzoyl Peroxide: Oral rat LD50 –>5,000 mg/kg, Inhalation rat LD50 ->24.3 mg/L/4hr

Oxybenzone: Oral rat LD50- >12,800 mg/kg, Skin rabbit LD50- >16000 mg/kg

Reproductive Toxicity Data: No data available. This product is not expected to cause adverse reproductive effects.

Specific Target Organ Toxicity (STOT):
Single Exposure: No data available.

Repeated Exposure: No data available.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:
Urethane Dimethacrylate: 96 hr LC50 Zebra fish- 10.1 mg/L, 48 hr EC50 Daphnia magna->1.2 mg/L
Amorphous Precipitated Silica: 24h EC50 Daphnia Magna: >10,000 mg/l; 96h LC50 Zebra Fish: >10,000 mg/l
Benzoyl Peroxide: 96 hr LC50 Rainbow Trout – 0.0602 mg/L; 48 hr EC50 Daphnia magna- 0.0602 mg/L (M-factor acute-10)
Oxybenzone: 96 hr LC50 Oryzias latipes – 3.8 mg/L, 48 hr EC50 Daphnia magna- 1.87 mg/L

This product is classified as toxic to the aquatic environment with long-term adverse effects. Releases to the environment should be avoided.

12.2 Persistence and Degradability: Urethane Dimethacrylate: Not readily degradable- 22% in 28 days. Benzoyl Peroxide: Readily biodegradable in screening tests – 68% in 28 days. Oxybenzone: Biodegradable 60-70% in 28 days.

12.3 Bio-accumulative Potential: No data is currently available

12.4 Mobility in Soil: No data is currently 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: Exposure to sunlight or artificial light will cause the material to polymerize into a hard plastic. Empty containers retain product residues 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): This product is a medical device and not subject to chemical notification requirements.

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
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%
Methanol	67-56-1	<1 ppm
Acetaldehyde	75-07-0	<0.225 ppm
1, 4-Dioxane	123-91-1	<0.125 ppm
Ethylene oxide acetaldehyde	75-21-8	<0.0125 ppm

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Medical devices are not subject to WHMIS.

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 – 0 Physical Hazard– 1

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

E Explosive
N Dangerous for the Environment.
O Oxidizing
Xi Irritant
R3 Extreme risk of explosion by shock, friction, fire or other sources of ignition.
R7 May cause fire.
R36 Irritating to the eyes.
R43 May cause sensitization by skin contact.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 Aquatic Acute Toxicity Category 1
Aquatic Acute 2 Aquatic Acute Toxicity Category 2
Aquatic Chronic 2 Aquatic Chronic Toxicity Category 2
Eye Irrit. 2 Eye Irritant Category 2
Flam. Liq. 4 Flammable Liquid Category 4
Org. Perox Type B Organic Peroxide Type B
Skin Sens. 1 Skin Sensitizer Category 1
H241 Heating may cause a fire or explosion.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H400 Very toxic to aquatic life.
H401 Toxic to aquatic life.
H411 Toxic to aquatic life with long lasting effects.

Supersedes: 6 March 2015
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Revision Summary: Corrected spelling error

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.