# **SAFETY DATA SHEETS**

# This SDS packet was issued with item:

072766616

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

072766863 072766871 072766889 072766897 072766905 072766913

# **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: 30 June 1997 Document Number: 099 Date Revised: 2 February 2012 Revision Number: 5

# 1. PRODUCT IDENTIFICATION

Trade Name (as labeled): Triad Reline Material (Original Flow)

Product Identifier (Part/Item Number): 9574501, 9574502,9574401,9574402,95757,95758.

U.N. Number:

U.N. Dangerous Goods Classification:

None

Recommended Use: Resin used in removable dental appliances

Restrictions on Use: For Professional Use Only

Manufacturer/Supplier Name: Dentsply Prosthetics

Manufacturer/Supplier Address: 570 West College Ave.

York, PA 17405-0872

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

**Emergency Contact Telephone Number:** 800-424-9300 Chemtrec

Email address: Prosthetics\_MSDS@Dentsply.com

# 2. HAZARD(s) IDENTIFICATION

EU Classification (1999/45/EC): Xi; R36/38, R43, R52/53

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

# Labeling in accordance with 1999/45/EC:



Irritant

R36/38 Irritating to eyes and skin.

R43 May cause sensitization by skin contact.

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical attention

S24/25 Avoid contact with skin and eyes.

S36/37 Wear suitable protective clothing and gloves.

S61 Avoid release to the environment. Refer to Safety data sheets.

US Hazard Classification: Hazardous.

# 3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. #	EINECS #	Substance Classification	WT %
Polymethylmethacrylate	Proprietary	Proprietary	Xi R36/38, R43	30-60
Dichlorodimethyl Silane-, reaction products with silica	68611-44-9	271-893-4	Not Applicable	10-20
1,6-Hexanediol Dimethylacrylate	6606-59-3	229-551-7	Xi N R36/37/38, R51/53	1-5
Urethane Dimethyacrylate	72869-86-4	276-957-5	R52/53	30-60

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

# 4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions	
Eye	Immediately flush victim's eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention.	
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation develops. Launder clothing before re-use. (Discard contaminated shoes).	
Inhalation	If irritation develops, remove to fresh air. Get medical attention if symptoms persist.	
Ingestion	If conscious, wash mouth out with water. Do not induce vomiting. Never give anything by mouth to an unconscious or convulsing person. Get medical attention.	
Most important symptoms of exposure	May cause eye and skin irritation. May cause skin sensitization.	
Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.		

# 5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Medi	a: Water fog, foam, carbon	Water fog, foam, carbon dioxide, water spray or dry chemical.		
Fire Fighting Procedures:	Cool exposed intact con	Cool exposed intact containers with water spray.		
Specific Hazards Arising fro the Chemical:		High temperatures and sunlight may cause a polymerizing reaction to occur.  Decomposition may release acrid smoke or fumes.		
Precautions for Fire Fighters		Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus.		
	Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	HANDS	RESPIRATORY	THERMAL	
			A	

# 6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: Avoid contact with skin, eyes or clothing.

**Environmental Precautions**: Spill and release reporting requirements vary. Consult local authorities regarding requirements. Prevent entry into sewers and waterways

**Methods and Materials for Containment and Clean-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.

EYES/FACE	HANDS	RESPIRATORY	SKIN

# 7. HANDLING AND STORAGE

**Precautions for Safe Handing:** Avoid contact with the eyes, skin and clothing. Wear protective clothing and equipment as described in Section 8. Use only 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.

**Conditions for Safe Storage:** 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.

# 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:			
Polymethylmethacrylate	United States	None Established	
	Germany	None Established	
	United Kingdom	None Established	
	European Union	None Established	

Dichlorodimethyl silane, reaction products with silica (as PNOC)	United States	15 mg/m3 TWA OSHA PEL (Total Dust) 5 mg/m3 TWA OSHA PEL (Respirable)
	Germany	4 mg/m <sup>3</sup> TWA DFG MAK (Inhalable) 1.5 mg/m <sup>3</sup> TWA DFG MAK (Respirable)
	United Kingdom	10 mg/m3 TWA UK OEL (Inhalable) 4 mg/m3 TWA UK OEL (Respirable)
	European Union	None Established
1,6-Hexanediol Dimethylacrylate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Urethane Dimethacrylate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established

Biological Exposure Limits: None Established

**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 chemical splash goggles recommended.

**Specific Skin Protection:** Wear impervious gloves such as rubber to prevent skin contact. Recommended glove: Rubber. Consult glove supplier for thickness and breakthrough times. Impervious clothing as needed to prevent contact.

**Specific Respiratory Protection:** None under normal use conditions. If the product is heated and ventilation is inadequate, wear an approved respirator appropriate for the exposure conditions.

**Specific Thermal Hazards:** None required.

# Recommended Personal Protective Equipment EYES/FACE HANDS RESPIRATORY SKIN One of the second protective Equipment of th

**Environmental Exposure Controls:** Do not allow spills to enter sewers or waterways.

**General Hygiene Considerations and Work Practices:** Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.

**Protective Measures During Repair and Maintenance of Contaminated Equipment:** Wear appropriate protective clothing and equipment.

# 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Fibered pink doughy material in the uncured state. Pink hard plastic when cured.	Explosive limits:	Not applicable
Odor:	Not available	Vapor pressure:	<1
Odor threshold:	Not available	Vapor density:	>1
pH:	Not determined	Relative density:	1.2
Melting/freezing point:	<-40°C(<-40°F)	Solubility:	Negligible
Initial boiling point and range:	Not applicable (polymerizes)	Partition coefficient: n-octanol/water:	Not available
Flash point:	Not applicable	Auto-ignition temperature:	Not applicable
Evaporation rate:	Not available	Decomposition temperature:	Not available
Flammability:	Not Flammable	Viscosity:	Not available
<b>Explosive Properties:</b>	None	Oxidizing Properties:	None
% Volatile by Volume:	Not available		

# 10. STABILITY AND REACTIVITY

Reactivity: Polymerization can occur.

Chemical Stability: Unstable if heated.

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

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

**Incompatible materials**: Avoid oxidizing agents, reducers and free radical generators. Avoid excessive heat, flames, ignition sources and direct sunlight

**Hazardous Decomposition Products**: Thermal decomposition may release Acrid fumes, carbon oxides, and methylmethacrylate.

# 11. TOXICOLOGICAL INFORMATION

# **Potential Health Effects:**

Eyes: May cause irritation, 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.

Chronic Health Effects: None expected under normal use.

<u>Carcinogenicity:</u> None of the components at 0.1% or greater are listed as possible carcinogens by NTP, IARC, ACGIH, the EU Dangerous Substances Directive, or OSHA.

Mutagenicity: No data available.

<u>Medical Conditions Aggravated by Exposure</u>: Individuals with pre-existing skin disorders may be at increased risk from exposure.

# **Acute Toxicity Data:**

Polymethylmethacrylate: No data available

Dichlorodimethyl Silane-, reaction products with silica: Oral Rat LD50: >5000 mg/kg

1,6-Hexanediol Dimethylacrylate: Oral rat LD50: >2000 mg/kg Urethane Dimethacrylate: Oral 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

**Toxicity**: 1,6-Hexanediol Dimethylacrylate: 96h/LC50 fish: 4.5 mg/l, Urethane Dimethacrylate: 96 hr LC50 Zebra fish >10,000 mg/L

Persistence and Degradability: 1,6-Hexanediol Dimethylacrylate: readily biodegradable

Urethane Dimethacrylate: not readily biodegradable

Bio-accumulative Potential: No data is currently available

Mobility in Soil: No data is currently available

Other Adverse Effects: No data is currently available

**Results of PBT/vPvB Assessment:** Not applicable.

# 13. DISPOSAL CONSIDERATIONS

**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 MSDS precautions when handling empty containers.

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

# 14. TRANSPORT INFORMATION

UN Number:	ADR/RID: None	IMDG: None	IATA: None	DOT: None
UN proper shipping name:	ADR/RID: Not Regu IMDG: Not Regulate IATA: Not Regulated DOT: Not Regulated	d l		
Transport hazard class(es):	ADR/RID: None	IMDG: None	IATA: None	DOT: None
Packaging group:	ADR/RID: None	IMDG: None	IATA: None	DOT: None
Environmental hazards:	ADR/RID: No	IMDG Marine pollutant: No	IATA: No	DOT: No
Special precautions fo	r user: Not applicable			

# 15. REGULATORY INFORMATION

# **U.S. Federal Regulations**

US OSHA Hazard Classification: Acute Health, Chronic Health

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

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:	Yes	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	0.02

# **International Regulations**

**Canadian Workplace Hazardous Materials Information System (WHMIS):** This product is a medical device and not subject to labeling under WHMIS.

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

**EU REACH:** All components requiring registration have been pre-registered.

**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.

**Korean Existing Chemicals List:** 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.

# 16. OTHER INFORMATION

# **HMIS Hazard Rating:**

Health –2 Flammability – 1 Physical Hazard – 1

EU Classes and Risk Phrases for Reference (See Sections 2 and 3):

Xi Irritant

N Dangerous for the Environment.

R36/38 Irritating to eyes and skin.

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

R43 May cause sensitization by skin contact.

R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Supersedes: 10 June 2009

Revision Summary: Change in format. Comprehensive review. Changes to all sections.

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

ESIS, Country websites for occupational exposure limits.

# **DENTSPLY International**

# **Prosthetics**

# Safety Data Sheet

Safety Data Sheet conforms to Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 2015/830, US 29CFR1910.1200, Canada Hazardous Products Regulation

Revision Number: 11

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

1.1 Product Identifier:

Trade Name (as labeled): Triad® Reline Material (Original Flow)

Part/Item Number: 9574501, 9574502, 9574401, 9574402, 95757, 95758

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 Sirona Prosthetics

Manufacturer/Supplier Address: 570 West College Ave.

York, PA 17401

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

Email address: Prosthetics\_MSDS@dentsplysirona.com

1.4 Emergency Telephone Number:

**Emergency Contact Telephone Number:** 800-243-1942

# 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		

# 2.2 Label Elements:



Signal Word: Warning

Date Issued: 30 June 1997

Date Revised: 28 February 2019

Document Number: 99

Contains: Urethane Dimethacrylate

Hazard Phrases	Precautionary Phrases
H317 May cause an allergic skin reaction.	P261 Avoid breathing dust or fume.
H411 Toxic to aquatic life with long lasting effects.	P272 Contaminated work clothing must not be allowed out
	of the workplace.
	P273 Avoid release to the environment.
	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.
	P362+P364 Take off contaminated clothing and wash it
	before reuse.
	P391 Collect spillage.
	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 # / REACH	Classification	WT %
		Registration #		
Polymethylmethacrylate	Proprietary	Proprietary	Not Applicable	30-60
Urethane Dimethacrylate	72869-86-4	276-957-5 /	Skin Sens. 1, H317	30-60
			Aquatic Acute 2, H401	
			Aquatic Chronic 2, H411	
Dichlorodimethyl Silane-, reaction products with silica	68611-44-9	271-893-4 /	Not Applicable	10-20
1,6-Hexanediol Dimethacrylate	6606-59-3	229-551-7 /	Eye Irrit. 2, H319	<3
			Skin Irrit. 2, H315	
			STOT SE 3, H335	
			Aquatic Acute 2, H401	
2-Hydroxyethyl methacrylate	868-77-9	212-782-2 /	Eye Irrit. 2, H319	< 0.5
			Skin Irrit. 2, H315	
			Skin Sens. 1, H317	
Methacrylic acid	79-41-4	201-204-4 /	Acute Tox. 3, H311	< 0.3
			Acute Tox. 4, H302, H332	
			Skin Corr. 1A, H314	
			Eye Dam. 1, H318	
			STOT SE 3, H335	
Benzoyl Peroxide	94-36-0	202-327-6 /	Org. Perox. B, H241	< 0.1
			Eye Irrit. 2, H319	
			Skin Sens. 1, H317	
			Aquatic Acute 1, H400	
			(M-Factor Acute: 10)	
			Aquatic Chronic 1, H410	
			(M-Factor Chronic: 10)	

The exact concentration is being withheld as a trade secret.

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

# 4. FIRST AID MEASURES

4.1 Description	4.1 Description of First Aid Measures:			
Eye	Rinse thoroughly with water. Get medical attention if irritation occurs and persists.			
Skin	Remove contaminated clothing and shoes. Flush skin thoroughly with water for several minutes. Get medical attention if irritation or rash occurs. Launder clothing before re-use.			
Inhalation	Remove victim to fresh air. If breathing is difficult or irritation persists, get medical attention.			
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:				

Prolonged or repeated contact may cause allergic skin reaction. 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.

# 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	Use media appropriate for surrounding fire.		
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/Precautions for Fire Fighters:	Cool fire exposed containers and structures with water. 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.		

# 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.

# **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. For dust, collect using a dustless method (HEPA vacuum or wet method) and place in appropriate container for use. Do not use compressed air. Do not sweep up. Flush spill area with water to remove residue.

# 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 Handling:

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.

**7.3 Specific End Use (s):** For professional use only.

# 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

# 8.1 Control Parameters: Occupational Exposure Limits:

Polymethylmethacrylate (as PNOC)	5 mg/m <sup>3</sup> (Respirable fraction), 15 mg/m <sup>3</sup> (total dust) TWA OSHA PEL		
	4 mg/m³ TWA DFG MAK (Inhalable)		
Urethane Dimethacrylate (as PNOC)	5 mg/m³ (Respirable fraction), 15 mg/m³ (total dust) TWA OSHA PEL		
	4 mg/m³ TWA DFG MAK (Inhalable)		
Dichlorodimethyl Silane-, reaction products with silica (as PNOC)	5 mg/m³ (Respirable fraction), 15 mg/m³ (total dust) TWA OSHA PEL		
	4 mg/m³ TWA DFG MAK (Inhalable)		
1,6-Hexanediol Dimethacrylate (as PNOC)	5 mg/m³ (Respirable fraction), 15 mg/m³ (total dust) TWA OSHA PEL		
	4 mg/m³ TWA DFG MAK (Inhalable)		
2-Hydroxyethyl methacrylate (as PNOC)	5 mg/m³ (Respirable fraction), 15 mg/m³ (total dust) TWA OSHA PEL		
	4 mg/m³ TWA DFG MAK (Inhalable)		
Methacrylic acid	20 ppm TWA ACGIH TLV		
	50 ppm TWA, 100 ppm STEL DFG MAK		
	20 ppm TWA, 40 ppm STEL UK WEL		
	20 ppm TWA Belgium OEL		

Benzoyl Peroxide	5 mg/m³ TWA ACGIH TLV
	5 mg/m³ TWA OSHA PEL
5 mg/m <sup>3</sup> TWA, 5 mg/m <sup>3</sup> STEL (inhalable) DFG MAK	
	5 mg/m³ TWA UK WEL
	5 mg/m³ TWA Belgium OEL

\*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 are recommended to avoid eye contact. In Europe follow EN 166.

**Specific Skin Protection:** Wear impervious gloves such to prevent prolonged skin contact. Contact your glove supplier for selection assistance. In Europe follow EN 374.

**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

# 9. PHYSICAL AND CHEMICAL PROPERTIES

# 9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Fibered pink doughy material in the uncured state. Pink hard plastic when cured.	Explosive limits:	LEL: Not applicable UEL: Not applicable
Odor:	Not available	Vapor pressure (mmHg):	<1
Odor threshold:	Not applicable	<b>Vapor density:</b> (Air = 1)	Not applicable
рН:	Not applicable	Relative density:	1.2
Melting/freezing point:	<-40°C (<-40°F)	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: (n-BuAc = 1)	Not available	Decomposition temperature:	Not available

Flammability (solid, gas):	Not applicable	Viscosity:	Not available
<b>Explosive Properties:</b>	Not explosive	Oxidizing Properties:	Not an oxidizer

**9.2 Other Information:** None available

# 10. STABILITY AND REACTIVITY

10.1 Reactivity: Polymerization can occur.

10.2 Chemical Stability: Unstable if heated.

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

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

**10.5 Incompatible materials:** Avoid oxidizing agents, reducers and free radical generators. Avoid excessive heat, flames, ignition sources and direct sunlight

**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: Contact with dust cause eye irritation with redness, burning and tearing.

<u>Skin:</u> Contact with dust may cause skin irritation. Prolonged contact may cause dermatitis. May cause allergic skin reaction (sensitization).

Ingestion: Ingestion may cause irritation of the mucous membranes, esophagus and stomach.

<u>Inhalation:</u> None expected under normal use. Inhalation of dust from grinding plastic or fumes may cause 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:** Urethane Dimethacrylate: Not irritating to rabbit skin and eyes. Methacrylic acid: Highly irritating to the rabbit eye.

Corrosivity: Methacrylic acid: Corrosive to rabbit skin.

<u>Sensitization:</u> Urethane Dimethacrylate: Sensitizing in Mouse local lymph node assay (LLNA). Individuals with sensitivity to methacrylates may develop an allergic reaction. Benzoyl Peroxide: Benzoyl peroxide 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.

Aspiration Hazard: Not an aspiration hazard.

# **Acute Toxicity Data:**

Polymethylmethacrylate: No toxicity data available Urethane Dimethacrylate: Oral rat LD50->5000 mg/kg

Dichlorodimethyl Silane-, reaction products with silica: Oral rat LD50->5000 mg/kg

1,6-Hexanediol Dimethacrylate: Oral rat LD50->2000 mg/kg

2-Hydroxyethyl methacrylate: Oral rat LD50- 5564 mg/kg, Skin rabbit LD50->5000 mg/kg

Methacrylic acid: Oral rat LD50- 1320 mg/kg, Inhalation rat LC50- 7.1 mg/L/4hr (as mist), Skin rabbit LD50- 500-1000 mg/kg

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

**Reproductive Toxicity Data:** No data available.

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

Specific Target Organ Toxicity Repeated Exposure (STOT-RE): 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, 72 hr EC50 Desmodesmus subspicatus- >0.68 mg/L, 14 day NOEC Microorganisms- activated sludge- ≥36.1 mg/L

Dichlorodimethyl Silane-, reaction products with silica: 96 hr LC50 Zebra fish->10000 mg/L, 24 hr EC50 Daphnia magna->10000 mg/L

1,6-Hexanediol Dimethacrylate: 96 hr LC50 Zebra fish- 4.5 mg/L

Methacrylic acid: 96 hr LC50 Rainbow trout- 85 mg/L, 48 hr EC50 Daphnia magna->130 mg/L

Benzoyl Peroxide: 96 hr LC50 Rainbow Trout – 0.06 mg/L, 48 hr EC50 Daphnia magna- 0.11 mg/L, 21 day EC10 Daphnia magna- 0.001 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. 1,6-Hexanediol Dimethacrylate: Readily degradable-91.1% in 28 days. Methacrylic acid: Readily biodegradable 86% in 28 days. Benzoyl Peroxide: Readily biodegradable in screening tests 68% 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:

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

# 14. TRANSPORT INFORMATION

14.1	UN 14.2 UN Proper Shipp	oing   14.3   14.4	Packing   14.5 Environmental
Num	ber Name	Hazard Grou	ıp Hazards

			Class(s)		
DOT	None	Not Regulated	None	None	None
ADR/RID	UN3082	Environmentally Hazardous	9	III	Yes
		Substance, solid, n.o.s.			
		(Urethane Dimethacrylate)			
IMDG	UN3082	Environmentally Hazardous	9	III	Marine Pollutant
		Substance, solid, n.o.s.			
		(Urethane Dimethacrylate)			
IATA/ICAO	UN3082	Environmentally Hazardous	9	III	Yes
		Substance, solid, n.o.s.			
		(Urethane Dimethacrylate)			

**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: See OSHA Hazard Classification in Section 2.

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372): None.

# **State Regulations**

**California:** This product can expose you to chemicals including Titanium Dioxide, which is known to the State of California to cause cancer, and Methanol, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to <a href="https://www.P65Warnings.ca.gov">www.P65Warnings.ca.gov</a>.

# **International Regulations**

**Canadian Environmental Protection Act:** 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.

Triad® Reline Material (Original Flow)

**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:

Acute Tox. 3 Acute Toxicity Category 3

Acute Tox. 4 Acute Toxicity Category 4

Aquatic Acute 1 Aquatic Acute Toxicity Category 1

Aquatic Acute 2 Aquatic Acute Toxicity Category 2

Aquatic Chronic 1 Aquatic Chronic Toxicity Category 1

Aquatic Chronic 2 Aquatic Chronic Toxicity Category 2

Eye Dam. 1 Eye Damage Category 1

Eye Irrit. 2 Eye Irritant Category 2

Org. Perox. B Organic Peroxide Type B

Skin Corr. 1A Skin Corrosion Category 1A

Skin Irrit. 2 Skin Irritant Category 2

Skin Sens. 1 Skin Sensitizer Category 1

STOT SE 3 Specific Target Organ Toxicity Single Exposure Category 3

H241 Heating may cause a fire or explosion.

H301 Toxic if swallowed.

H302 Harmful if swallowed.

H311 Toxic in contact with skin.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H400 Very toxic to aquatic life.

H401 Toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

H411 Toxic to aquatic life with long lasting effects.

Supersedes: 5 February 2019 Date Updated: 28 February 2019

Revision Summary: Change to Section 1.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA REACH Registration Website,

Country websites for occupational exposure limits.