

SAFETY DATA SHEETS

This SDS packet was issued with item:

072767184

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).

072767143 072767168 072767176 072767192 072767200

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: 19 July 2005
Document Number: 100
Date Revised: 20 December 2011
Revision Number: 4

1. PRODUCT IDENTIFICATION

Trade Name (as labeled):	Triad® Gel
Product Identifier (Part/Item Number):	88859, 88860, 88750, 88751, 88762
U.N. Number:	Not Regulated
U.N. Dangerous Goods Classification:	Not Regulated
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): Irritant (Xi)

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.
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.

US Hazard Classification: Hazardous

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. #	EINECS #	Substance Classification	WT %
Aliphatic Urethane Methacrylate	Proprietary	Proprietary	Xi R36/38, R43	80-100%
Amorphous Precipitated Silica	112945-52-5	231-545-4	Not Applicable	1-10%

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





4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions
Eye	Immediately flush with water for 15 minutes. Get medical attention.
Skin	Remove contaminated clothing. Wash with soap and water. If irritation develops and persists, get medical attention.
Inhalation	If irritation develops, remove to fresh air. Get medical attention if symptoms persist.
Ingestion	If swallowed, wash mouth with water. DO NOT induce vomiting. 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 Media:	Use water fog, foam, carbon dioxide, water spray or dry chemical.
Fire Fighting Procedures:	Cool exposed intact containers with water spray.
Specific Hazards Arising from the Chemical:	High temperatures may cause a polymerizing reaction to occur. Closed containers may rupture or explode during runaway polymerization.
Precautions for Fire Fighters:	Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus in fires involving chemicals.

Recommended Protective Equipment for Fire Fighters:

EYES/FACE	HANDS	RESPIRATORY	THERMAL
			



6. ACCIDENTAL RELEASE MEASURES

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

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local, state and federal authorities.

Methods and Materials for Containment and Clean-up: Exposure to sunlight or artificial light will cause the gel to polymerize into hard plastic. Spread the gel to maximize the surface area. Once the material is hard, pick up and place into a container for disposal.

Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE	HANDS	RESPIRATORY	THERMAL
			

7. HANDLING AND STORAGE

Precautions for Safe Handling: Avoid contact with eyes, skin and clothing. Wash hands thoroughly before eating, drinking, smoking, or using the toilet facilities. Remove contaminated clothing and launder before reuse. Keep out of the reach of children.

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. Refrigeration prolongs shelf life. Store away from food or beverages.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:

Aliphatic Urethane Methacrylate	United States	Aliphatic Urethane Methacrylate
	Germany	Aliphatic Urethane Methacrylate
	United Kingdom	Aliphatic Urethane Methacrylate
	European Union	Aliphatic Urethane Methacrylate

Amorphous Precipitated Silica	United States	3 mg/m ³ (respirable fraction) TWA , 10 mg/m ³ (inhalable) TWA ACGIH TLV 5 mg/m ³ (respirable fraction) TWA, 15 mg/m ³ (total dust) TWA OSHA PEL
	Germany	4 mg/m ³ TWA (inhalable) DFG MAK
	United Kingdom	2.4 mg/m ³ TW (respirable), 6 mg/m ³ TWA (inhalable) UK OEL
	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.

Individual Protection Measures (PPE)



Specific Eye/face Protection: Chemical safety glass or chemical splash goggles.

Specific Skin Protection: Wear rubber gloves to avoid skin contact. Clothing with long sleeves may be needed when working with large quantities. Recommended glove: Rubber Consult glove supplier for thickness and breakthrough times.

Specific Respiratory Protection: None should be needed for normal use. If the product is heated and ventilation is inadequate, wear a NIOSH approved respirator appropriate for the level of exposure. For firefighting, use self-contained breathing apparatus.

Specific Thermal Hazards: None needed.

Recommended Personal Protective Equipment

EYES/FACE	HANDS	RESPIRATORY	THERMAL
			

Environmental Exposure Controls: None required for normal use.

General Hygiene Considerations and Work Practices: Wash thoroughly after handling. Wear impervious clothing as needed to avoid contamination of personal clothing.

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, red, blue, or pink, colorless, gels	Explosive limits:	LEL: Not applicable UEL: Not applicable
Odor:	Slight ester odor.	Vapor pressure:	<1 mmHg
Odor threshold:	Not available	Vapor density:	>1
pH:	Not applicable	Relative density:	1.2

Melting/freezing point:	<-40°C (<-40°F)	Solubility:	Negligible
Initial boiling point and range:	Not available	Partition coefficient: n-octanol/water:	Not available
Flash point:	Not flammable	Auto-ignition temperature:	Not available
Evaporation rate:	Not available	Decomposition temperature:	Not available
Flammability:	Not flammable	Viscosity:	90,000 cps @ 40°C (140°F)
Explosive Properties:	Not explosive	Oxidizing Properties:	None
% Volatile by Volume:	Negligible		

10. STABILITY AND REACTIVITY

Reactivity: Non-reactive

Chemical Stability: Stable

Possibility of Hazardous Reactions: Will polymerize in contact with sunlight or artificial light.

Conditions to Avoid: Avoid high temperatures and direct sunlight.

Incompatible materials: Oxidizing agents, reducing agents, free radical imitators, inert gases and oxygen scavengers. Avoid excessive heat, flames, ignition sources and direct sunlight.

Hazardous Decomposition Products: Acrid fumes, carbon and nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

Potential Health Effects:

Eyes: May cause irritation with redness and tearing. Repeated contact may cause moderate irritation.

Skin: May cause irritation with redness and rash. Repeated contact may cause moderate irritation with redness and swelling. May cause allergic skin reaction or sensitization.

Ingestion: None expected under normal conditions of use.

Inhalation: None expected under normal conditions of use.

Chronic Health Effects: Repeated eye contact may cause moderate irritation. Repeated skin contact may cause moderate irritation with redness and swelling. May cause allergic skin reaction or sensitization.

Carcinogenicity: None of the components are listed as carcinogens by OSHA, IARC or NTP, ACGIH or the EU substances directive.

Mutagenicity: No data available. This product is not expected to cause mutagenic activity.

Medical Conditions Aggravated by Exposure: Individuals with chronic skin disorders may be at increased risk from exposure to this material.

Acute Toxicity Data:

Aliphatic Urethane Methacrylate: No data available.

Amorphous Precipitated Silica: Oral Rat LD50: >10,000 mg/kg, Inhalation Rat LC50: >0.139 mg/l/4 hrs (highest concentration – no deaths), Skin Rabbit LD50: >5,000 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

Toxicity: No toxicity data available. This product is not expected to cause environmental toxicity. .

Persistence and Degradability: No data is currently available.

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: No data is currently available.

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 gel to polymerize into a hard plastic.

Waste Treatment Recommendations: Not applicable

14. TRANSPORT INFORMATION

UN Number:	ADR/RID: None	IMDG: None	IATA: None	DOT: None
UN proper shipping name:	ADR/RID: Not Regulated IMDG: Not Regulated IATA: Not Regulated DOT: Not Regulated			
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 for user: Not applicable				

15. REGULATORY INFORMATION

U.S. Federal Regulations

US OSHA Hazard Classification: Irritant, Sensitizer.

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 chemical(s) known to the State of California to cause cancer, birth defects or reproductive harm:

Components	C.A.S. #	WT %
None		

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Class D 2B (Very toxic material causing other chronic effects)

European Inventory of Existing Chemicals (EINECS): 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.

Japanese Existing and New 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

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

Xi Irritant

R36/38 - Irritating to eyes and skin.

R43 – May cause sensitization by skin contact

Supersedes: 11 September 2008

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

Safety Data Sheet

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

Date Issued: 19 July 2005
Document Number: 100
Date Revised: 2 August 2017
Revision Number: 6

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

1.1 Product Identifier:

Trade Name (as labeled): Triad® Gel
Part/Item Number: 88859, 88860, 88750, 88751, 88762

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: 800-424-9300 Chemtrec

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:		
Health	Environmental	Physical
Eye Irritant Category 2 (H319) Skin Irritant Category 2 (H315) Skin Sensitization Category 1 (H317)	Not Hazardous	Not Hazardous

2.2 Label Elements:



Signal Word: Warning

Contains: Aliphatic Urethane Methacrylate

Hazard Phrases	Precautionary Phrases
H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation.	P261 Avoid breathing mist or vapor. P264 Wash thoroughly after handling. P272 Contaminated work clothing must not be allowed out of the workplace. P280 Wear protective gloves, protective clothing, eye protection and face 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. P363 + P364 Take off contaminated clothing and wash it 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 # / REACH Registration #	Classification	WT %
Aliphatic Urethane Methacrylate	Proprietary	Proprietary	Eye Irrit. 2A, H319 Skin Irrit. 2, H315 Skin Sens. 1, H317	80-100%
Amorphous Precipitated Silica	112945-52-5	231-545-4 /	Not Applicable	1-10%

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 of First Aid Measures:

Eye	Flush eyes with large quantities of water for at least 15 minutes, while holding the eyelids apart. Get medical attention if irritation persists.
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water. If rash, irritation or symptoms develop, get medical attention. Launder clothing before re-use. (Discard contaminated shoes).
Inhalation	If irritation develops, remove to fresh air. Get medical attention if symptoms persist.
Ingestion	If small quantities are swallowed, wash mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious or drowsy person. Get medical attention if symptoms develop or if you feel

	unwell.
4.2 Most Important Symptoms and Effects, Both Acute and Delayed:	
May cause moderate eye and skin irritation. May cause skin sensitization.	
4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:	
Immediate medical attention is not required.	

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 may cause a polymerizing reaction to occur. Closed containers may rupture or explode during runaway polymerization. Decomposition may release acrid smoke or fumes, carbon and nitrogen oxides.	
5.3 Advice for Fire-Fighters:	
Fire Fighting Procedures/Precautions for Fire Fighters:	Cool exposed intact containers with water spray. Firefighters should wear full emergency equipment and an approved positive pressure self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:	
Evacuate spill area and keep unprotected personnel away. Avoid contact with skin, eyes or clothing. Avoid breathing vapors or mists. Ventilate area. Wear appropriate protective clothing as described in Section 8.	
6.2 Environmental Precautions:	
Prevent entry into sewers and waterways. Report releases as required by local, state and federal authorities.	
6.3 Methods and Material for Containment and Cleaning up:	
Exposure to sunlight or artificial light will cause the gel to polymerize into hard plastic. Spread the gel 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 Handling:	
Avoid contact with the eyes, skin and clothing. Wear protective clothing and equipment as described in Section 8. Avoid breathing vapors or mists. Use with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use. Keep out of the reach of children.	
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. Material is light sensitive, do not store in direct sunlight. 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:

Aliphatic Urethane Methacrylate	None Established
Amorphous Precipitated Silica	20 mppcf TWA OSHA PEL
	4 mg/m ³ TWA DFG MAK (Inhalable)
	6 mg/m ³ (Inhalable), 2.4 mg/m ³ (respirable) TWA UK WEL

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 and when grinding polymerized (cured) material.

Individual Protection Measures (PPE):

Specific Eye/face Protection: Chemical safety goggles recommended.

Specific Skin Protection: Impervious gloves such as rubber recommended.

Specific Respiratory Protection: None should be needed for normal use. If the exposure limits are exceeded, 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:	Colorless, red, blue, or pink viscous gel	Explosive limits:	LEL: Not applicable UEL: Not applicable
Odor:	Slight ester odor.	Vapor pressure (mmHg):	<1 mmHg
Odor threshold:	Not available	Vapor density: (Air=1)	>1
pH:	Not applicable	Relative density:	1.2

Melting/freezing point:	<-40°C (<-40°F)	Solubility(ies):	Negligible in water
Initial boiling point and boiling range:	Not available	Partition coefficient: n-octanol/water:	Not available
Flash point:	Not flammable	Auto-ignition temperature:	Not available
Evaporation rate:	Not available	Decomposition temperature:	Not available
Flammability (solid, gas):	Not applicable	Viscosity:	90,000 cps @ 40°C (104°F)
Explosive Properties:	Closed containers may explode due to runaway polymerization.	Oxidizing Properties:	None

9.2 Other Information: None available.

10. STABILITY AND REACTIVITY

10.1 Reactivity: Will react when exposed to heat or light.

10.2 Chemical Stability: Stable under normal conditions.

10.3 Possibility of Hazardous Reactions: Hazardous polymerization will occur when exposed to high temperatures, sunlight, or artificial light.

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

10.5 Incompatible materials: Oxidizing agents, reducing agents, free radical imitators, inert gases and oxygen scavengers. Avoid excessive heat, flames, ignition sources and direct sunlight.

10.6 Hazardous Decomposition Products: Decomposition may release acrid smoke or fumes, carbon and nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Contact may cause irritation with redness, tearing and stinging. Repeated contact may cause moderate irritation.

Skin: May cause irritation with redness and rash. Repeated contact may cause moderate irritation with redness and swelling. May cause an allergic skin reaction or sensitization.

Ingestion: None expected under normal conditions of use.

Inhalation: None expected under normal conditions of use.

Chronic Health Effects: None known.

Irritation: No data available. This product is expected to cause eye and skin irritation.

Corrosivity: No data available. This product is not expected to be corrosive.

<u>Sensitization:</u> No data available. This product is not expected to cause sensitization.
<u>Carcinogenicity:</u> None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.
<u>Mutagenicity:</u> No data available. This product is not expected to cause mutagenic activity.
Aspiration Hazard: Not an aspiration hazard
<u>Acute Toxicity Data:</u> Aliphatic Urethane Methacrylate: No toxicity data available. 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
<u>Reproductive Toxicity Data:</u> No data available. This product is not expected to cause adverse reproductive effects.
<u>Specific Target Organ Toxicity Single Exposure (STOT-SE):</u> No data available.
<u>Specific Target Organ Toxicity Repeated Exposure (STOT-RE):</u> No data available.

12. ECOLOGICAL INFORMATION

12.1 Toxicity: Amorphous Precipitated Silica: 24h EC50 Daphnia Magna: >10,000 mg/l; 96h LC50 Zebra Fish: >10,000 mg/l This product is not expected to cause environmental toxicity.
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:

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	No
ADR/RID	None	Not Regulated	None	None	No
IMDG	None	Not Regulated	None	None	No
IATA/ICAO	None	Not Regulated	None	None	No

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.

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: Classified under OSHA Hazcom 2012 GHS as per 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 contains the following substances known to the state of California to cause cancer and/or reproductive toxicity: None known.

International Regulations

Canadian Environmental Protection Act: 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.

Japanese Existing and New 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.

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:

Eye Irrit. 2A Eye Irritant Category 2A

Skin Irrit. 2 Skin Irritant Category 2

Skin Sens. 1 Skin Sensitization Category 1

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

Supersedes: 30 April 2014

Date Updated: 2 August 2017

Revision Summary: 3 Year update. Changes to all sections.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA REACH Registration Website, Country websites for occupational exposure limits.