

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

071734243

**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).**

071734219 071734227 071734235 071734326

**DENTSPLY/International**  
**DENTSPLY/Caulk**  
**Material Safety Data Sheet**

**51D898**

**1. Product and Company Identification**

Product Name <b>iNterra™ Nightguard</b>	MSDS Code Number <b>51D898</b>
Trade Name & Synonyms <b>iNterra™ INoffice Nightguard</b>	Date of Last Revision <b>01/15/08</b>
Chemical Name <b>Dimethacrylate Resins</b>	Manufacturer <b>DENTSPLY/Caulk</b>
C.A.S. Number Not Applicable	Address <b>38 West Clarke Avenue Milford DE 19963-1805 <a href="http://www.caulk.com">http://www.caulk.com</a></b>
Grades or Minor Variant Identities Not Applicable	Information Telephone Number <b>(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)</b>
Product Use (for Canada) Not Applicable	Emergency Telephone Number <b>(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)</b>

**2. Composition Of Ingredients**

Hazardous Components	C.A.S. Number	Exposure Limits	%
Acrylated Urethane Dimethacrylate	Proprietary	Not Established	40 – 50
Aliphatic Ester Urethane Dimethacrylate	Proprietary	Not Established	10 – 20
Urethane Methacrylate	Proprietary	Not Established	10 – 15
Methacrylate Ester	Proprietary	Not Established	3 – 5
Acrylate Ester	Proprietary	Not Established	1 – 5
Acrylate polymer	Proprietary	Not Established	10 – 15

**3. Hazard Identification**

Emergency Overview: Uncured product may cause eye irritation. Dust from grinding cured product may cause mechanical eye irritation and upper respiratory tract irritation. Uncured material is irritating to skin.					
EU Preparation Classification (1999/45/EC): Xi R36					
Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s)	Target Organ(s)
Eye	Material can cause irritation.	Single	Moderate	Irritation and possible corneal damage	Not Applicable
Skin	Material may be an irritant	Single & Repeated	Moderate	Irritation or possible allergic response. Severe allergic response may result in breathing difficulties.	Not Applicable
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Ingestion	Material is probably not harmful if swallowed	Not Applicable	Mild	Not Applicable	Not Applicable
Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Medical Conditions Aggravated by Exposure Open sores and wounds of the skin. Individuals with known sensitivity to methacrylates, acrylates, or urethane dimethacrylate resin used in Dental products.					
Carcinogenicity: NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No					
All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.					
Potential Environmental Effects Do not allow paste to enter sewers/ surface or ground water.					
HMIS Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 1, Reactivity = 1					

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**4. First Aid Measures**

Routes of Exposure	First Aid Instructions	Immediate Medical Attention	Delayed Effects
Eye	Immediately flush victim's eyes with large quantities of water, holding the eyelids apart. Get medical attention if irritation persists.	Not Applicable	Not Applicable
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation develops. Launder contaminated clothing before re-use.	Not Applicable	Not Applicable
Inhalation	Remove victim to fresh air. Get medical attention if irritation develops.	Not Applicable	Not Applicable
Ingestion	If small quantities are swallowed, rinse out mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious or drowsy person. If irritation or discomfort occurs, get immediate medical attention.	Not Applicable	Not Applicable
Other	Not Applicable	Not Applicable	Not Applicable

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

**5. Fire and Explosion Data**

Flashpoint: >356°F (180°C)	Flammable (Explosive) Limits in Air LEL: Not Applicable UEL: Not Applicable	Autoignition Temperature: Not Established	Other: Not Applicable
Flame Propagation or Burning Rate (for Solids): Not Applicable	Properties Contributing to Fire Intensity: Not Applicable	Flammability Classification: Not Applicable	
Extinguishing Media: CO <sub>2</sub> , foam or dry chemical.		Extinguishing Media to Avoid: Water with full jet.	
Protection and Procedures for Firefighters: Firefighters should wear full emergency equipment and NIOSH approved positive pressure self-contained breathing apparatus. Cool exposed containers with water spray.			
Unusual Fire and Explosion Hazards: High temperatures and sunlight may cause a polymerizing reaction to occur. Decomposition may release acrid smoke or fumes.			

**6. Accidental Release Measures**

Containment Techniques: Material is a paste and as such will not flow.		
Spill/Leak Clean-up Procedures and Equipment: Avoid gross skin contact to minimize the possibility of contact dermatitis to susceptible persons. Ensure adequate ventilation. Wear protective clothing. If product is uncured, expose to sunlight or artificial light to cause the resin to polymerize. Pick up cured material and place into a container for disposal.		
Evacuation Procedures: Not Applicable	Special Instructions: Not Applicable	Reporting Requirements: Not Applicable

**7. Handling and Storage**

Handling Practices and Warnings: Avoid contact with the eyes, skin and clothing. Wear protective clothing and equipment as described in section 8. Wash thoroughly with soap and water after handling. Keep container closed when not in use. Avoid breathing dust of cured material. Use with adequate ventilation. Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals. Empty containers retain product residues can be hazardous. Follow all MSDS precautions when handling empty containers.	
Storage Practices and Warnings: Store in a tightly closed container in a cool, well-ventilated area. Material is light sensitive. Light will cause product to polymerize. Do not store in direct sunlight or near excessive heat. Protect from physical damage. Keep away from oxidizers and other incompatible materials.	

**8. Exposure Control / Personal Protection**

Ventilation: None required during normal intended use of this product.		Engineering Controls: None normally needed. When grinding or polishing, use local exhaust ventilation to minimize dust exposure levels.
Routes of Entry	Personal Protective Equipment (PPE) for Normal Use	PPE for Emergencies
Eye/Face	None needed under normal use conditions. Wear safety glasses when grinding or polishing	Not Applicable
Skin	The glove material has to be impermeable and resistant to the product. Wear latex, PVC or other impervious gloves to minimize skin contact.	Not Applicable
Inhalation	Not Required in normal use. When grinding, polishing or where exposure levels are excessive, 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 appropriate regulations and good hygiene practice.	Not Applicable
Body Protection	Impervious clothing as needed to prevent contact. An eyewash should be available in the immediate work area.	Not Applicable
General Hygiene Considerations and Work Practices: Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at end of work. Avoid contact with the eyes and skin.		
Protective Measures During Repair and Maintenance of Contaminated Equipment: Not Applicable		
Other Protective Measures and Equipment: Not Applicable		

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**9. Physical and Chemical Characteristics**

Appearance: Clear semi solid.		Odor: Characteristic acrylate odor.
Normal Physical State: Very High Viscosity Liquid (Paste)		Melting Point: <-40°C (-40°F)
Specific Gravity: 1.1 g/cm <sup>3</sup>	Solubility in Water: Not miscible	pH: Not Applicable
Vapor Pressure (mm Hg): Negligible	Vapor Density (AIR=1): Not determined	Evaporation Rate (Butyl Acetate =1): Not Applicable
Other: Not Applicable		

**10. Stability and Reactivity Data**

Incompatibility (Materials to Avoid): Avoid contact with strong oxidizers, amines, halogens and bases.		
Hazardous Products Produced During Decomposition: Carbon monoxide, carbon dioxide, silicone dioxide, barium oxide and hydrogen fluoride.		
Hazardous Polymerization: <input type="checkbox"/> May Occur <input checked="" type="checkbox"/> May Not Occur	Conditions to Avoid: Elevated temperatures and direct sunlight.	
Stability? <input checked="" type="checkbox"/> Stable <input type="checkbox"/> Unstable	Conditions to Avoid: None known	

**11. Toxicological Information**

Potential Health Effects:	
<b>Eyes:</b> Direct contact may cause irritation with redness, burning and tearing. Dust from grinding or polishing may cause mechanical irritation.	
<b>Skin:</b> Uncured product may cause mild irritation or cause contact dermatitis on prolonged contact. Not irritating in primary skin irritation studies. The cured and uncured product tested negative in a Kligman Maximization Test with guinea pigs. Repeated or prolonged contact with the unpolymerized material may cause sensitization for persons allergic to acrylates and methacrylates used in dental materials.	
<b>Inhalation:</b> Dust from grinding or polishing may cause sneezing, coughing and other signs of mechanical irritation.	
<b>Ingestion:</b> No adverse effects are expected from swallowing small amount. This product was found to be non-toxic in tests with laboratory animals.	
<b>Chronic Health Effects:</b> Prolonged or repeated skin contact with uncured material may cause skin irritation or sensitization in some individuals.	
<b>Carcinogenicity:</b> None of the components are listed as carcinogens by OSHA, IARC, or NTP.	
<b>Mutagenicity:</b> The cured product tested negative in the Ames Mutagenicity Test.	
<b>Medical Conditions Aggravated by Exposure:</b> Individuals with pre-existing respiratory disorders may be at increased risk from exposure.	
<b>Acute Toxicity Data:</b> Tests were conducted on cured and uncured extracts in water and sesame oil in mice. A single dose of 40 ml/kg was gavaged and the animals were observed for 14 days for any signs of toxicity. Under the conditions of the study, the extracts were not considered toxic.	

**12. Ecological Information**

<p>Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water streams or sewage system.</p>
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**13. Disposal Considerations**

<p>Regulations: Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Larger quantities should be disposed of in accordance with Federal, State and Local regulations. This product will polymerize when exposed to sunlight. Small gram amounts can be allowed to polymerize to a hard solid and then disposed of normally.</p>
Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.

**14. Transport Information**

Regulated for Shipping: No. Not Regulated	DOT Shipping Name: Not Regulated	Packing Group: Not Applicable
Do Changes in Quantities, packaging, or shipment method change product classification? No	DOT Hazard Class: Not Applicable	UN Number: Not Applicable

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**15.Regulatory Information**

U.S. Federal Regulations: CERCLA 103 Reportable Quantity: 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

Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None

SARA TITLE III: Hazard Category for Section 311/312: Acute Health.

Section 302 Extremely Hazardous Substances (TPQ): None

EPA Toxic Substances Control Act (TSCA) Status: This product is a medical device and is not subject to chemical notification requirements. All of the components of this product are listed on the TSCA inventory.

U.S. State Regulations California Proposition 65: This product contains the following substance known to the state of California to cause reproductive toxicity (birth defects) Toluene <32 ppm.

International Regulations: Canadian Environmental Protection Act:

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

Canadian WHMIS Classification: Medical devices are not subject to WHMIS requirements.

European Community Labeling: IRRITANT: R36 Irritating to eyes. S25 Avoid contact with eyes. S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical attention.

EU Classes and Risk Phrases for Reference: Xi Irritant, R36 Irritating to eyes. R36/38 Irritating to eyes and skin. R43 May cause irritation by skin contact.

European Inventory of New and Existing Chemicals Substances (EINECS):

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

Other: Not Applicable

**16.Other Information**

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex.

All components are synthetically produced; none are derived from animal products.

# DENTSPLY Milford

## Safety Data Sheet

**51D898**

### 1. Identification

Product Name <b>iNterra™</b>	SDS Code Number <b>51D898</b>
Substance Identity <b>iNterra™ INoffice Nightguard</b>	Date of Last Revision <b>05/05/16</b>
Manufacturer: <b>DENTSPLY Milford</b>	Address <b>38 West Clarke Avenue Milford DE 19963-1805 <a href="http://www.dentsply.com">http://www.dentsply.com</a></b>
Grades or Minor Variant Identities <b>Not Applicable</b>	Information Telephone Number <b>(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)</b>
Product Use (for Canada) <b>Not Applicable</b>	Emergency Telephone Number <b>(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)</b>

### 2. Hazard(s) Identification



**WARNING**

**CAUSES SKIN IRRITATION**

**Wash hands thoroughly after handling.**

**Wear protective gloves.**

**IF ON SKIN: Wash with plenty of soap and water.**

**If skin irritation occurs: Get Medical Advice/attention.**

**Take off contaminated clothing and wash before reuse.**

### 3. Composition/Information on Ingredients

Hazardous Components	C.A.S. Number	Exposure Limits	%
Acrylated Urethane Dimethacrylate	Proprietary	Not Established	40 – 50
Aliphatic Ester Urethane Dimethacrylate	Proprietary	Not Established	10 – 20
Urethane Methacrylate	Proprietary	Not Established	10 – 15
Methacrylate Ester	Proprietary	Not Established	3 – 5
Acrylate Ester	Proprietary	Not Established	1 – 5
Acrylate polymer	Proprietary	Not Established	10 – 15

### 4. First Aid Measures

Routes of Exposure	First Aid Instructions	Immediate Medical Attention	Delayed Effects
Eye	Immediately flush victim's eyes with large quantities of water, holding the eyelids apart. Get medical attention if irritation persists.	Not Applicable	Not Applicable
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation develops. Launder contaminated clothing before re-use.	Not Applicable	Not Applicable
Inhalation	Remove victim to fresh air. Get medical attention if irritation develops.	Not Applicable	Not Applicable
Ingestion	If small quantities are swallowed, rinse out mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious or drowsy person. If irritation or discomfort occurs, get immediate medical attention.	Not Applicable	Not Applicable
Mucosa	Immediately flush victim's eyes with large quantities of water, holding the eyelids apart. Get medical attention if irritation persists.	Not Applicable	Not Applicable
Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically.			

### 5. Fire Fighting Measures

Flashpoint: >356°F (180°C)	Flammable (Explosive) Limits in Air LEL: Not Applicable UEL: Not Applicable	Autoignition Temperature: Not Established	Other: Not Applicable
Flame Propagation or Burning Rate (for Solids): Not Applicable	Properties Contributing to Fire Intensity: Not Applicable	Flammability Classification: Not Applicable	
Extinguishing Media: CO <sub>2</sub> , foam or dry chemical.		Extinguishing Media to Avoid: Water with full jet.	

Protection and Procedures for Firefighters: Firefighters should wear full emergency equipment and NIOSH approved positive pressure self-contained breathing apparatus. Cool exposed containers with water spray.

Unusual Fire and Explosion Hazards: High temperatures and sunlight may cause a polymerizing reaction to occur. Decomposition may release acrid smoke or fumes.

## 6. Accidental Release Measures

Containment Techniques: Material is a paste and as such will not flow.

Spill/Leak Clean-up Procedures and Equipment: Avoid gross skin contact to minimize the possibility of contact dermatitis to susceptible persons. Ensure adequate ventilation. Wear protective clothing. If product is uncured, expose to sunlight or artificial light to cause the resin to polymerize. Pick up cured material and place into a container for disposal.

Evacuation Procedures: Not Applicable

Special Instructions: Not Applicable

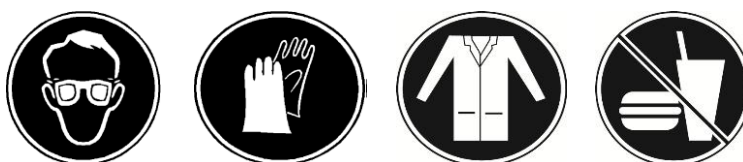
Reporting Requirements: Not Applicable

## 7. Handling and Storage

Handling Practices and Warnings: Avoid contact with the eyes, skin and clothing. Wear protective clothing and equipment as described in section 8. Wash thoroughly with soap and water after handling. Keep container closed when not in use. Avoid breathing dust of cured material. Use with adequate ventilation. Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals. Empty containers retain product residues can be hazardous. Follow all MSDS precautions when handling empty containers.

Storage Practices and Warnings: Store in a tightly closed container in a cool, well-ventilated area. Material is light sensitive. Light will cause product to polymerize. Do not store in direct sunlight or near excessive heat. Protect from physical damage. Keep away from oxidizers and other incompatible materials.

## 8. Exposure Control / Personal Protection



Ventilation: None required during normal intended use of this product.

Engineering Controls: None normally needed. When grinding or polishing, use local exhaust ventilation to minimize dust exposure levels.

Individual Protection Measures	Personal Protective Equipment for Normal Use	Personal Protective Equipment for Emergencies
Eye/Face	None needed under normal use conditions. Wear safety glasses when grinding or polishing	Not Applicable
Skin	The glove material has to be impermeable and resistant to the product. Wear latex, PVC or other impervious gloves to minimize skin contact.	Not Applicable
Inhalation	Not Required in normal use. When grinding, polishing or where exposure levels are excessive, 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 appropriate regulations and good hygiene practice.	Not Applicable
Body Protection	Impervious clothing as needed to prevent contact. An eyewash should be available in the immediate work area.	Not Applicable

General Hygiene Considerations and Work Practices: Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at end of work. Avoid contact with the eyes and skin.

Protective Measures During Repair and Maintenance of Contaminated Equipment: Not Applicable

Other Protective Measures and Equipment: Not Applicable

## 9. Physical and Chemical Characteristics

Appearance: Clear semi solid.	Odor: Characteristic acrylate odor.
Normal Physical State: Very High Viscosity Liquid (Paste)	Melting Point: <-40°C(-40°F)
Specific Gravity: 1.1 g/cm <sup>3</sup>	Solubility in Water: Not miscible
Vapor Pressure (mm Hg): Negligible	pH: Not Applicable
	Evaporation Rate (Butyl Acetate =1): Not Applicable
Other: Not Applicable	

## 10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Avoid contact with strong oxidizers, amines, halogens and bases.
Hazardous Products Produced During Decomposition: Carbon monoxide, carbon dioxide, silicone dioxide, barium oxide and hydrogen fluoride.
Hazardous Polymerization: <input type="checkbox"/> May Occur <input checked="" type="checkbox"/> May Not Occur
Stability? <input checked="" type="checkbox"/> Stable <input type="checkbox"/> Unstable
Conditions to Avoid: Elevated temperatures and direct sunlight.
Conditions to Avoid: None known

## 11. Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data:

Product is an irritant to the skin and mucous membranes.

Potential Health Effects:

<p><b>Eyes:</b> Direct contact may cause irritation with redness, burning and tearing. Dust from grinding or polishing may cause mechanical irritation.</p> <p><b>Skin:</b> Uncured product may cause mild irritation or cause contact dermatitis on prolonged contact. Not irritating in primary skin irritation studies. The cured and uncured product tested negative in a Kligman Maximization Test with guinea pigs. Repeated or prolonged contact with the unpolymerized material may cause sensitization for persons allergic to acrylates and methacrylates used in dental materials.</p> <p><b>Inhalation:</b> Dust from grinding or polishing may cause sneezing, coughing and other signs of mechanical irritation.</p> <p><b>Ingestion:</b> No adverse effects are expected from swallowing small amount. This product was found to be non-toxic in tests with laboratory animals.</p> <p><b>Chronic Health Effects:</b> Prolonged or repeated skin contact with uncured material may cause skin irritation or sensitization in some individuals.</p> <p><b>Carcinogenicity:</b> None of the components are listed as carcinogens by OSHA, IARC, or NTP.</p> <p><b>Mutagenicity:</b> The cured product tested negative in the Ames Mutagenicity Test.</p> <p><b>Medical Conditions Aggravated by Exposure:</b> Individuals with pre-existing respiratory disorders may be at increased risk from exposure.</p> <p><b>Acute Toxicity Data:</b> Tests were conducted on cured and uncured extracts in water and sesame oil in mice. A single dose of 40 ml/kg was gavaged and the animals were observed for 14 days for any signs of toxicity. Under the conditions of the study, the extracts were not considered toxic.</p> <p>Emergency Overview Material is irritating to eyes, respiratory system and skin.</p>					
Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s)	Target Organ(s)
Eye	Material can cause irritation.	Single	Moderate	Irritation and possible corneal damage	Not Applicable
Skin	Material may be an irritant	Single & Repeated	Moderate	Irritation or possible allergic response. Severe allergic response may result in breathing difficulties.	Not Applicable
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Ingestion	Material is not harmful if swallowed using clinically relevant quantities	Not Applicable	Mild	Not Applicable	Not Applicable
Mucosa	Material can cause irritation.	Single	Mild	Inflammation of the mucosa	Not Applicable
Medical Conditions Aggravated by Exposure Open sores and wounds of the skin. Individuals with known sensitivity to methacrylates, acrylates, or urethane dimethacrylate resin used in Dental restorative products.					
Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.					
Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.					
NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 1, Reactivity = 0					

## 12. Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water streams or sewage system.

## 13. Disposal Considerations

Regulations: Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Larger quantities should be disposed of in accordance with Federal, State and Local regulations. This product will polymerize when exposed to sunlight. Small gram amounts can be allowed to polymerize to a hard solid and then disposed of normally.

Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.

## 14. Transport Information

Regulated for Shipping: No. Not Regulated	DOT Shipping Name: Not Regulated	Packing Group: Not Applicable
Do Changes in Quantities, packaging, or shipment method change product classification? No	DOT Hazard Class: Not Applicable	UN Number: Not Applicable

## 15. Regulatory Information

This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations.
U.S. Federal Regulations: CERCLA 103 Reportable Quantity: 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
Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None
SARA TITLE III: Hazard Category for Section 311/312: Acute Health.
Section 302 Extremely Hazardous Substances (TPQ): None
EPA Toxic Substances Control Act (TSCA) Status: This product is a medical device and is not subject to chemical notification requirements. All of the components of this product are listed on the TSCA inventory.
U.S. State Regulations California Proposition 65: This product contains the following substance known to the state of California to cause reproductive toxicity (birth defects) Toluene <32 ppm.
International Regulations: Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.
Canadian WHMIS Classification: Medical devices are not subject to WHMIS requirements.
European Community Labeling: IRRITANT: R36 Irritating to eyes. S25 Avoid contact with eyes. S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical attention.
EU Classes and Risk Phrases for Reference: Xi Irritant, R36 Irritating to eyes. R36/38 Irritating to eyes and skin. R43 May cause irritation by skin contact.



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

## **16.Other Information**

<p>To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex. All components are synthetically produced; none are derived from animal products. This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific products features and shall not establish a legally valid contractual relationship. The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer. For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.</p>
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