

## **SAFETY DATA SHEETS**

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

071719020

**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).**

071718659 071718683

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

**523899**

**1. Identification**

Product Name <b>DYCAL<sup>®</sup> Radiopaque Calcium Hydroxide Composition</b>	SDS Code Number <b>523899</b>
Substance Identity <b>DYCAL<sup>®</sup> Radiopaque Calcium Hydroxide Composition</b>	Date of Last Revision <b>04/15/11</b>
Manufacturer: <b>DENTSPLY Caulk</b>	Address <b>38 West Clarke Avenue Milford DE 19963-1805 http://www.caulk.com http://www.dentsply.com</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 - Base Paste**

Hazardous Components	C.A.S. Number	Exposure Limits	%
Calcium Tungstate	7790-75-2	5 mg/M <sup>3</sup>	< than 20
Zinc Oxide	1314-13-2	10 mg/M <sup>3</sup>	< than 15
Disalicylate ester of 1,3 butylene glycol	73240-13-8	Not Established	< than 50

Other Information: Colorants are synthetic inorganic iron oxides.

**3. Composition/Information on Ingredients - Catalyst Paste**

Hazardous Components	C.A.S. Number	Exposure Limits	%
Calcium Hydroxide	1305-62-0	5 mg/M <sup>3</sup>	< than 55
Zinc Oxide	1314-13-2	10 mg/M <sup>3</sup>	< than 15
Titanium Dioxide	13463-67-7	10 mg/M <sup>3</sup>	< than 10

**3. Hazard Identification**

Emergency Overview: Material is an irritant.					
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 may cause irritation.	Single & Repeated	Moderate	Irritation and possible corneal damage due to the caustic nature of ingredient used in the product.	Not Applicable
Skin	Material may cause irritation.	Single & Repeated	Mild	Irritation or possible allergic response.	Not Applicable
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Ingestion	Material may cause irritation.	Not Applicable	Mild	Irritation due to the caustic nature of ingredients used in the product.	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.					
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 = 0, Reactivity = 0

#### 4. First Aid Measures

Routes of Exposure	First Aid Instructions	Immediate Medical Attention	Delayed Effects
Eye	Rinse opened eye for several minutes under running water. If symptoms persist consult physician.	Not Applicable	Not Applicable
Skin	Immediately wash with soap and water and rinse thoroughly.	Not Applicable	Not Applicable
Inhalation	Supply fresh air, If symptoms persist consult physician. This may not be of concern when using clinically relevant quantities.	Not Applicable	Not Applicable
Ingestion	Rinse out mouth and then drink plenty of water. Consult a physician immediately. This may not be of concern when using clinically relevant quantities.	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 Method: Not Applicable	Flammable (Explosive) Limits in Air LEL: Not Applicable UEL: Not Applicable	Autoignition Temperature: Not Applicable	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: Use fire extinguishing methods suitable to surrounding conditions.		Extinguishing Media to Avoid: Not Applicable	
Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.			
Unusual Fire and Explosion Hazards: Formation of toxic gases is possible during heating or in case of fire.			

#### 6. Accidental Release Measures

Containment Techniques: Material is a high viscosity paste, but will flow somewhat.		
Spill/Leak Clean-up Procedures and Equipment: Absorb with liquid binding material (sand, vermiculite, diatomite, acid binders, universal binders or sawdust). Scoop up bulk material and place in a labeled plastic or metal container.		
Evacuation Procedures: Not Applicable	Special Instructions: Not Applicable	Reporting Requirements: Not Applicable

#### 7. Handling and Storage

Handling Practices and Warnings: 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.
Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Store away from food and beverages.

#### 8. Exposure Control / Personal Protection



Individual Protection Measures	Personal Protective Equipment for Normal Use	Personal Protective Equipment for Emergencies
Eye/Face	Safety Glasses	Not Applicable
Skin	The glove material has to be impermeable and resistant to the product.	Not Applicable
Inhalation	Not Required. This may not be of concern when using clinically relevant quantities.	Not Applicable
Body Protection	Protective work clothing	Not Applicable
Occupational Exposure Limits: Not Applicable		Engineering Controls: Not Applicable

#### 9. Physical and Chemical Characteristics

Appearance: Base-light yellow colored paste, catalyst-white paste.	Odor: Base odor of cloves, Catalyst Odorless.
Normal Physical State: Paste	Melting Point: Not Applicable
Specific Gravity: Base 2.0 g/cm <sup>3</sup> Catalyst 1.8 g/cm <sup>3</sup>	pH: Base-Not Applicable, Catalyst- 11.5
Vapor Pressure (mm Hg): Not Applicable	Vapor Density (AIR=1): Not Applicable
Flashpoint - Method: Not Applicable	Evaporation Rate (Butyl Acetate =1): Not Applicable
	Autoignition Temperature: Not Applicable
Other: Not Applicable	

#### 10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Not Applicable	
Hazardous Products Produced During Decomposition: Not Applicable	
Hazardous Polymerization: <input type="checkbox"/> May Occur <input checked="" type="checkbox"/> May Not Occur	Conditions to Avoid: None known
Stability? <input checked="" type="checkbox"/> Stable <input type="checkbox"/> Unstable	Conditions to Avoid: None known

#### 11. Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data:
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Obtained by Global Safety Management, Inc. -Tel: 1-813-435-5161 - www.globalsafety.net.com

Irritating to skin and mucous membranes.					
Emergency Overview: Material is an irritant.					
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 may cause irritation.	Single & Repeated	Moderate	Irritation and possible corneal damage due to the caustic nature of ingredient used in the product.	Not Applicable
Skin	Material may cause irritation.	Single & Repeated	Mild	Irritation or possible allergic response.	Not Applicable
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Ingestion	Material may cause irritation.	Not Applicable	Mild	Irritation due to the caustic nature of ingredients used in the product.	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.					
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: Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.					
NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 0, 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. Toxic to fish. Also poisonous for fish and plankton in water bodies. Toxic for aquatic organisms.



Danger  
Hazardous to aquatic life

## 13. Disposal Considerations

Regulations: Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations  
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
Section 302 Extremely Hazardous Substances (TPQ): None
EPA Toxic Substances Control Act (TSCA) Status: All of the components of this product are listed on the TSCA inventory.
U.S. State Regulations California Proposition 65: This product does not contain any chemicals, which are on the California Proposition 65 list.
International Regulations: Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.
European Community Labeling: Not a dangerous preparation. These R and S phrases apply to base and catalyst: R36/38 Irritating to eyes and skin. R51/53 Toxic to aquatic organisms, may cause long-term effects in the environment. S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S28 After contact with skin, wash immediately with plenty of water. S37 Wear suitable gloves. S57 Use appropriate container to avoid environmental contamination. S60 This material and its container must be disposed of as hazardous waste. These R and S phrases apply to catalyst: R41 Risk of serious damage to eyes. R50/53 Very toxic to aquatic organisms, may cause long-term effects in the environment. S24 Avoid contact with skin.
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. 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.



## Document Detail

**Type:** 0070-SDS  
**Document No.:** 0070-GR523899[3]  
**Title:** Dycal SDS  
**Comment**  
**Status:** CURRENT  
**Effective Date:** 08-Jul-2019

## Approvals

<u>Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
Milford Document Control	Michelle Wilson	26-Jun-2019 12:02 pm	GMT
Milford Research & Development Approver	Huaibing Liu	27-Jun-2019 12:51 pm	GMT
Milford EHS Approver	Colby Landiss	01-Jul-2019 1:32 pm	GMT
Milford Design & Development Engineering Approver	David West	26-Jun-2019 1:27 pm	GMT
Milford QA_RA Approver	Karen Trovalli	27-Jun-2019 3:22 pm	GMT
Milford External DPD Approver	Heather Shellenberger	26-Jun-2019 1:10 pm	GMT
Milford EHS Approver	Anthony Milbut	01-Jul-2019 5:51 pm	GMT
Milford Website Approver	Sabine Dabisch	04-Jul-2019 10:08 am	GMT
Milford External DPD Approver	Lucy Brenneman	08-Jul-2019 3:28 pm	GMT
Milford External DeTrey (Konstanz) Approver	Susanne Bachmeier	04-Jul-2019 10:24 am	GMT
Milford Research & Development Approver	Barbara Colburn	08-Jul-2019 1:42 pm	GMT



# DentsplySirona Safety Data Sheet

523899

## 1. Identification

Product Name <b>DYCAL® Radiopaque Calcium Hydroxide Composition</b>	SDS Code Number <b>523899</b>
Substance Identity <b>DYCAL® Radiopaque Calcium Hydroxide Composition</b>	Date of Last Revision <b>06/24/19</b>
Manufacturer: <b>DENTSPLY Caulk</b>	Address <b>38 West Clarke Avenue Milford DE 19963-1805 <a href="http://www.dentsplysirona.com">http://www.dentsplysirona.com</a></b>
Grades or Minor Variant Identities <b>Not Applicable</b>	Company Telephone Number (Product Inquiries) (302) <b>422-4511 (8:00 AM – 4:30 PM Eastern Time)</b>
Product Use (for Canada) <b>Not Applicable</b>	Emergency Telephone Number <b>CHEMTREC: 1-800-424-9300 (24 hours) (Outside U.S. +1-703-527-3887) CCN6510</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 - Base Paste

Hazardous Components	C.A.S. Number	Exposure Limits	%
Calcium Tungstate	7790-75-2	5 mg/M <sup>3</sup>	< than 20
Zinc Oxide	1314-13-2	10 mg/M <sup>3</sup>	< than 15
Disalicylate ester of 1,3 butylene glycol	73240-13-8	Not Established	< than 50

Other Information: Colorants are synthetic inorganic iron oxides.

## 3. Composition/Information on Ingredients - Catalyst Paste

Hazardous Components	C.A.S. Number	Exposure Limits	%
Calcium Hydroxide	1305-62-0	5 mg/M <sup>3</sup>	< than 55
Zinc Oxide	1314-13-2	10 mg/M <sup>3</sup>	< than 15
Titanium Dioxide	13463-67-7	10 mg/M <sup>3</sup>	< than 10

## 3. Hazard Identification

Emergency Overview: Material is an irritant.					
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 may cause irritation.	Single & Repeated	Moderate	Irritation and possible corneal damage due to the caustic nature of ingredient used in the product.	Not Applicable
Skin	Material may cause irritation.	Single & Repeated	Mild	Irritation or possible allergic response.	Not Applicable
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Ingestion	Material may cause irritation.	Not Applicable	Mild	Irritation due to the caustic nature of ingredients used in the product.	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.					

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 = 0, Reactivity = 0				

#### 4. First Aid Measures

Routes of Exposure	First Aid Instructions	Immediate Medical Attention	Delayed Effects
Eye	Rinse opened eye for several minutes under running water. If symptoms persist consult physician.	Not Applicable	Not Applicable
Skin	Immediately wash with soap and water and rinse thoroughly.	Not Applicable	Not Applicable
Inhalation	Supply fresh air. If symptoms persist consult physician. This may not be of concern when using clinically relevant quantities.	Not Applicable	Not Applicable
Ingestion	Rinse out mouth and then drink plenty of water. Consult a physician immediately. This may not be of concern when using clinically relevant quantities.	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 Method: Not Applicable	Flammable (Explosive) Limits in Air LEL: Not Applicable UEL: Not Applicable	Autoignition Temperature: Not Applicable	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: Use fire extinguishing methods suitable to surrounding conditions.		Extinguishing Media to Avoid: Not Applicable	
Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.			
Unusual Fire and Explosion Hazards: Formation of toxic gases is possible during heating or in case of fire.			

#### 6. Accidental Release Measures

Containment Techniques: Material is a high viscosity paste, but will flow somewhat.		
Spill/Leak Clean-up Procedures and Equipment: Absorb with liquid binding material (sand, vermiculite, diatomite, acid binders, universal binders or sawdust). Scoop up bulk material and place in a labeled plastic or metal container.		
Evacuation Procedures: Not Applicable	Special Instructions: Not Applicable	Reporting Requirements: Not Applicable

#### 7. Handling and Storage

Handling Practices and Warnings: 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.
Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Store away from food and beverages.

#### 8. Exposure Control / Personal Protection



Individual Protection Measures	Personal Protective Equipment for Normal Use	Personal Protective Equipment for Emergencies
Eye/Face	Safety Glasses	Not Applicable
Skin	The glove material has to be impermeable and resistant to the product.	Not Applicable
Inhalation	Not Required. This may not be of concern when using clinically relevant quantities.	Not Applicable
Body Protection	Protective work clothing	Not Applicable
Occupational Exposure Limits: Not Applicable		Engineering Controls: Not Applicable

#### 9. Physical and Chemical Characteristics

Appearance: Base-light yellow colored paste, catalyst-white paste.	Odor: Base odor of cloves, Catalyst Odorless.
Normal Physical State: Paste	Melting Point: Not Applicable
Specific Gravity: Base 2.0 g/cm <sup>3</sup> Catalyst 1.8 g/cm <sup>3</sup>	Solubility in Water: Not soluble
Vapor Pressure (mm Hg): Not Applicable	pH: Base-Not Applicable, Catalyst- 11.5
Flashpoint - Method: Not Applicable	Evaporation Rate (Butyl Acetate =1): Not Applicable
	Autoignition Temperature: Not Applicable
Other: Not Applicable	

#### 10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Not Applicable	
Hazardous Products Produced During Decomposition: Not Applicable	
Hazardous Polymerization: <input type="checkbox"/> May Occur <input checked="" type="checkbox"/> May Not Occur	Conditions to Avoid: None known
Stability? <input checked="" type="checkbox"/> Stable <input type="checkbox"/> Unstable	Conditions to Avoid: None known

#### 11. Toxicological Information



Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data: Irritating to skin and mucous membranes.					
Emergency Overview: Material is an irritant.					
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 may cause irritation.	Single & Repeated	Moderate	Irritation and possible corneal damage due to the caustic nature of ingredient used in the product.	Not Applicable
Skin	Material may cause irritation.	Single & Repeated	Mild	Irritation or possible allergic response.	Not Applicable
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Ingestion	Material may cause irritation.	Not Applicable	Mild	Irritation due to the caustic nature of ingredients used in the product.	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.					
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: Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.					
NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 0, Reactivity = 0					

## 12. Ecological Information

<p>Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class I (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. Toxic to fish. Also poisonous for fish and plankton in water bodies. Toxic for aquatic organisms.</p>
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Danger

Hazardous to aquatic life

## 13. Disposal Considerations

<p>Regulations: Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations</p>
<p>Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.</p>

## 14. Transport Information

	DOT	ADR/RID	IMDG	ICAO / IATA
UN number	None	3082	3082	3082
UN proper shipping name	Not regulated	Environmentally hazardous substance, liquid, n.o.s. (contains zinc oxide)	Environmentally hazardous substance, liquid, n.o.s. (contains zinc oxide)	Environmentally hazardous substance, liquid, n.o.s. (contains zinc oxide)
Transport hazard class	None	9	9	9
Packing group	None	III	III	III
Environmental Hazards	Yes	Yes	Yes	Yes

## 15. Regulatory Information

<p>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.</p>
<p>U.S. Federal Regulations: <u>CERCLA 103 Reportable Quantity</u>: 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</p>
<p><u>Section 313 Toxic Chemicals</u>: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None</p>
<p>Section 302 Extremely Hazardous Substances (TPQ): None</p>
<p><u>EPA Toxic Substances Control Act (TSCA) Status</u>: All of the components of this product are listed on the TSCA inventory.</p>
<p>U.S. State Regulations <u>California Proposition 65</u>: This product does not contain any chemicals, which are on the California Proposition 65 list.</p>
<p><u>International Regulations: Canadian Environmental Protection Act</u>: This product is a medical device and not subject to chemical notification requirements.</p>
<p><u>European Community Labeling</u>: Not a dangerous preparation. These R and S phrases apply to base and catalyst: R36/38 Irritating to eyes and skin. R51/53 Toxic to aquatic organisms may cause long-term effects in the environment. S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S28 After contact with skin, wash immediately with plenty of water. S37 Wear suitable gloves. S57 Use appropriate container to avoid environmental contamination. S60 This material and its container must be disposed of as hazardous waste. These R and S phrases apply to catalyst: R41 Risk of serious damage to eyes. R50/53 Very toxic to aquatic organisms, may cause long-term effects in the environment. S24 Avoid contact with skin.</p>
<p><u>European Inventory of New and Existing Chemicals Substances (EINECS)</u>: This product is a medical device and not subject to chemical notification requirements.</p>
<p>Other: Not Applicable</p>

## **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.

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.