

SAFETY DATA SHEETS

This SDS packet was issued with item:

071744028

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).

071742279 071742303 071742337 071743418 071743434 071743442 071743459 071743475 071743491 071743509
071743517 071743525 078292603 078292606 078293303 078293306 078293403 078293406

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

508058

1. Identification

Product Name JELTRATE®	SDS Code Number 508058
Substance Identity JELTRATE® Alginate Impression Material	Date of Last Revision 09/11/12
Manufacturer: DENTSPLY Caulk	Address 38 West Clarke Avenue Milford DE 19963-1805 http://www.caulk.com http://www.dentsply.com
Grades or Minor Variant Identities Fast Set and Regular Set	Information Telephone Number (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)
Product Use (for Canada) Dental Alginate Impression Material	Emergency Telephone Number (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)

2. Hazard(s) Identification



Danger

**May cause cancer by inhalation
May causes damage to lungs through
prolonged or repeated exposure**



Warning

Causes skin irritation

Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Use personal protective equipment required.
If exposed or concerned: Get medical attention.
Store locked up.
Dispose of contents/container in accordance with local regulations
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	%
Silicon Dioxide -Crystalline - Cristobalite	14464-46-1	0.025 mg/M ³	< than 26
Silicon Dioxide - Crystalline -Quartz	14808-60-7	0.025 mg/M ³	< than 3
Silicon Dioxide – Amorphous - Diatomaceous Earth	68855-54-9	0.1 mg/M ³	< than 35
Calcium Sulfate	10101-41-4	10 mg/M ³	< than 20
Magnesium Oxide	1309-48-4	10 mg/M ³	< than 7
Tetrasodium Pyrophosphate	7722-88-5	5 mg/M ³	< than 3

Colorant Information: Fast Set Product contains D & C Red # 30 Aluminum Lake as colorant.

Regular Set Product contains synthetic Yellow Iron Oxide as colorant.

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	Not Applicable	Not Applicable

	thoroughly		
Inhalation	Supply fresh air, consult physician if symptoms persist	Not Applicable	Irritation and soreness in throat and nose. In extreme exposures some congestion may occur. Inhalation of crystalline silica has been classified by IARC as carcinogenic for humans (Group 1). Inhalation of crystalline silica is also a known cause of silicosis, a non-cancerous lung disease caused by excessive exposure to crystalline silica. Respirable dust from this product may contain up to 26 % free crystalline silica (Cristobalite) and up to 3% crystalline silica (Quartz). As such it represents a risk to the respiratory system. Long term, unprotected exposure to dust levels in excess of the TLV or PEL may cause lung disease (silicosis).
Ingestion	If symptoms persist consult physician	Not Applicable	Low order of toxicity is expected when material is ingested.
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: Not Applicable		Extinguishing Media to Avoid: Water with full jet.	
Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.			
Unusual Fire and Explosion Hazards: In common with most inorganic / organic materials, this product should be treated as a combustible dust in the finely divided and suspended state. No dangerous decomposition products known. - Product does not present an explosion hazard.			

6. Accidental Release Measures

Containment Techniques: Material is a dry fluffy powder, which is colored pale yellow or pink. Store only in the original package. Keep package tightly sealed to minimize dust generation and accumulation. The avoidance of any air contaminant is always a recommended practice. Adherence to work place ventilation standards is an assurance of general personnel health and comfort		
Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container. Avoid gross skin contact to minimize the possibility of drying out the skin. Ensure adequate ventilation, by either natural or mechanical means to keep dust level below PEL.		
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. Protect from exposure to direct light. Store in a cool dry area. Store away from food and beverages. Minimize dust generation and accumulation. Avoid breathing dust and contact with eyes. Return cap to canisters immediately. Close pouches immediately after use. Continue to follow all MSDS/label warnings when handling empty containers. Observe normal warehouse handling procedures. The avoidance of any air contaminant is always a recommended practice. Adherence to work place ventilation standards is an assurance of general personnel health and comfort.

8. Exposure Control / Personal Protection



Ventilation: Ensure adequate ventilation, by either natural or mechanical means to keep dust level below PEL.		Other Engineering Controls: Not Applicable
Routes of Entry	Personal Protective Equipment (PPE) for Normal Use	PPE for Emergencies
Eye/Face	Safety Glasses	Not Applicable
Skin	The glove material has to be impermeable and resistant to the product.	Not Applicable
Inhalation	Recommended NIOSH approved nuisance dust mask. <10X PEL, use 3M 9900; <100X PEL, use MSA Ultra-Twin with H filter; <200X PEL, use MSA 01-00-06 with type C supplied air unit (continuous flow mode); or equivalent. Use sufficient natural or mechanical ventilation to keep dust level below PEL.	Not Applicable
Body Protection	Protective work clothing such as lab coat.	Not Applicable
General Hygiene Considerations and Work Practices: Avoid dusting when in use. 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. Do not eat, drink or smoke when using.		
Protective Measures During Repair and Maintenance of Contaminated Equipment: Not Applicable		
Other Protective Measures and Equipment: Not Applicable		

9. Physical and Chemical Characteristics

Appearance: Dry fluffy powder. May be colored pink or light yellow.	Odor: Spearmint odor.	
Normal Physical State: Dry fluffy powder.	Melting Point: Not Applicable	
Specific Gravity: 0.3 g/cm ³	Solubility in Water: Partially soluble	pH: Not Applicable
Vapor Pressure (mm Hg): Not Applicable	Vapor Density (AIR=1):	Evaporation Rate (Butyl Acetate =1): Not Applicable
Other: Not Applicable		

10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Hydrofluoric Acid.		
Hazardous Products Produced During Decomposition: No dangerous decomposition products known if used according to Directions for Use. (DFU).		
Hazardous Polymerization: ☐ May Occur ☒ May Not Occur	Conditions to Avoid: None known	
Stability? ☒ Stable ☐ Unstable	Conditions to Avoid: None known	

11.Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data: Inhalation of crystalline silica has been classified by IARC as carcinogenic for humans (Group1). Inhalation of crystalline silica is also a known cause of silicosis, a non-cancerous lung disease caused by excessive exposure to crystalline silica. Respirable dust from this product may contain up to 26 % free crystalline silica (Cristobalite). As such it represents a risk to the respiratory system. Long term, unprotected exposure to dust levels in excess of the TLV or PEL may cause lung disease (silicosis). The dry product may irritate the skin by drying it out.					
Emergency Overview: Inhalation of crystalline silica has been classified by IARC as carcinogenic for humans (Group 1). Inhalation of crystalline silica is also a known cause of silicosis, a non-cancerous lung disease caused by excessive exposure to crystalline silica. Respirable dust from this product may contain up to 26 % crystalline silica (Cristobalite) and up to 3% crystalline silica (Quartz). As such, it represents a risk to the respiratory system. Long term, unprotected exposure to dust levels in excess of the TLV or PEL may cause lung disease (silicosis).					
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.	Not Applicable
Inhalation	Transitory upper respiratory irritation or eye irritation.	Single & Repeated	Moderate	Irritation and soreness in throat and nose. In extreme exposures some congestion may occur. Inhalation of crystalline silica has been classified by IARC as carcinogenic for humans (Group1). Inhalation of crystalline silica is also a known cause of silicosis, a non-cancerous lung disease caused by excessive exposure to crystalline silica. Respirable dust from this product may contain up to 26 % free crystalline silica (Cristobalite) and up to 3 % crystalline silica (Quartz). As such it represents a risk to the respiratory system. Long term, unprotected exposure to dust levels in excess of the TLV or PEL may cause lung disease (silicosis).	Lung
Ingestion	Material is probably not harmful if swallowed	Not Applicable	Mild	Low order of toxicity is expected when material is ingested.	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?: Yes Group 1 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 = 3, 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.

13.Disposal Considerations

Regulations: Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations. Vacuum clean dust with equipment fitted with a HEPA filter. Use dust suppression such as water if sweeping is necessary. Sweep up spilled material and place in closed containers for disposal.
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: <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
<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
<u>Section 302 Extremely Hazardous Substances (TPQ)</u> : None
<u>EPA Toxic Substances Control Act (TSCA) Status</u> : All of the components of this product are listed on the TSCA inventory.
<u>U.S. State Regulations California Proposition 65</u> :
Warning: This product contains silica, crystalline (airborne particles of respirable size) which is known by the State of California to cause cancer.
<u>International Regulations: Canadian Environmental Protection Act</u> :
This product is a medical device and not subject to chemical notification requirements.
<u>European Community Labeling</u> : Not a dangerous preparation.
<u>European Inventory of New and Existing Chemicals Substances (EINECS)</u> :
This product is a medical device and not subject to chemical notification requirements.

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.

**DENTSPLY/International
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Safety Data Sheet**

508058

1. Identification

Product Name JELTRATE®	SDS Code Number 508058
Substance Identity JELTRATE® Alginate Impression Material	Date of Last Revision 08/25/15
Manufacturer: DENTSPLY Caulk	Address 38 West Clarke Avenue Milford DE 19963-1805 http://www.caulk.com http://www.dentsply.com
Grades or Minor Variant Identities Fast Set and Regular Set	Information Telephone Number (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)
Product Use (for Canada) Dental Alginate Impression Material	Emergency Telephone Number (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)

2. Hazard(s) Identification



Danger

**May cause cancer by inhalation
May causes damage to lungs through
prolonged or repeated exposure**



Warning

Causes skin irritation

Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Use personal protective equipment required.
If exposed or concerned: Get medical attention.
Store locked up.
Dispose of contents/container in accordance with local regulations
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	%
Silicon Dioxide -Crystalline - Cristobalite	14464-46-1	0.025 mg/M ³	< than 26
Silicon Dioxide - Crystalline -Quartz	14808-60-7	0.025 mg/M ³	< than 3
Silicon Dioxide – Amorphous - Diatomaceous Earth	68855-54-9	0.1 mg/M ³	< than 35
Calcium Sulfate	10101-41-4	10 mg/M ³	< than 20
Magnesium Oxide	1309-48-4	10 mg/M ³	< than 7
Tetrasodium Pyrophosphate	7722-88-5	5 mg/M ³	< than 3

Colorant Information: Fast Set Product contains D & C Red # 30 Aluminum Lake as colorant.

Regular Set Product contains synthetic Yellow Iron Oxide as colorant.

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	Not Applicable	Not Applicable

	thoroughly		
Inhalation	Supply fresh air, consult physician if symptoms persist	Not Applicable	Irritation and soreness in throat and nose. In extreme exposures some congestion may occur. Inhalation of crystalline silica has been classified by IARC as carcinogenic for humans (Group1). Inhalation of crystalline silica is also a known cause of silicosis, a non-cancerous lung disease caused by excessive exposure to crystalline silica. Respirable dust from this product may contain up to 26 % free crystalline silica (Cristobalite) and up to 3% crystalline silica (Quartz). As such it represents a risk to the respiratory system. Long term, unprotected exposure to dust levels in excess of the TLV or PEL may cause lung disease (silicosis).
Ingestion	If symptoms persist consult physician	Not Applicable	Low order of toxicity is expected when material is ingested.
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: Not Applicable		Extinguishing Media to Avoid: Water with full jet.	
Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.			
Unusual Fire and Explosion Hazards: In common with most inorganic / organic materials, this product should be treated as a combustible dust in the finely divided and suspended state. No dangerous decomposition products known. - Product does not present an explosion hazard.			

6. Accidental Release Measures

Containment Techniques: Material is a dry fluffy powder, which is colored pale yellow or pink. Store only in the original package. Keep package tightly sealed to minimize dust generation and accumulation. The avoidance of any air contaminant is always a recommended practice. Adherence to work place ventilation standards is an assurance of general personnel health and comfort		
Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container. Avoid gross skin contact to minimize the possibility of drying out the skin. Ensure adequate ventilation, by either natural or mechanical means to keep dust level below PEL.		
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. Protect from exposure to direct light. Store in a cool dry area. Store away from food and beverages. Minimize dust generation and accumulation. Avoid breathing dust and contact with eyes. Return cap to canisters immediately. Close pouches immediately after use. Continue to follow all MSDS/label warnings when handling empty containers. Observe normal warehouse handling procedures. The avoidance of any air contaminant is always a recommended practice. Adherence to work place ventilation standards is an assurance of general personnel health and comfort.

8. Exposure Control / Personal Protection



Ventilation: Ensure adequate ventilation, by either natural or mechanical means to keep dust level below PEL.		Other Engineering Controls: Not Applicable
Routes of Entry	Personal Protective Equipment (PPE) for Normal Use	PPE for Emergencies
Eye/Face	Safety Glasses	Not Applicable
Skin	The glove material has to be impermeable and resistant to the product.	Not Applicable
Inhalation	Recommended NIOSH approved nuisance dust mask. <10X PEL, use 3M 9900; <100X PEL, use MSA Ultra-Twin with H filter; <200X PEL, use MSA 01-00-06 with type C supplied air unit (continuous flow mode); or equivalent. Use sufficient natural or mechanical ventilation to keep dust level below PEL.	Not Applicable
Body Protection	Protective work clothing such as lab coat.	Not Applicable
General Hygiene Considerations and Work Practices: Avoid dusting when in use. 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. Do not eat, drink or smoke when using.		
Protective Measures During Repair and Maintenance of Contaminated Equipment: Not Applicable		
Other Protective Measures and Equipment: Not Applicable		

9. Physical and Chemical Characteristics

Appearance: Dry fluffy powder. May be colored pink or light yellow.		Odor: Spearmint odor.
Normal Physical State: Dry fluffy powder.		Melting Point: Not Applicable
Specific Gravity: 0.3 g/cm ³	Solubility in Water: Partially soluble	pH: Not Applicable
Vapor Pressure (mm Hg): Not Applicable	Vapor Density (AIR=1):	Evaporation Rate (Butyl Acetate =1): Not Applicable
Other: Not Applicable		

10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Hydrofluoric Acid.		
Hazardous Products Produced During Decomposition: No dangerous decomposition products known if used according to Directions for Use. (DFU).		
Hazardous Polymerization: ☐ May Occur ☒ May Not Occur	Conditions to Avoid: None known	
Stability? ☒ Stable ☐ Unstable	Conditions to Avoid: None known	

11.Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data: Inhalation of crystalline silica has been classified by IARC as carcinogenic for humans (Group1). Inhalation of crystalline silica is also a known cause of silicosis, a non-cancerous lung disease caused by excessive exposure to crystalline silica. Respirable dust from this product may contain up to 26 % free crystalline silica (Cristobalite). As such it represents a risk to the respiratory system. Long term, unprotected exposure to dust levels in excess of the TLV or PEL may cause lung disease (silicosis). The dry product may irritate the skin by drying it out.					
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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.	Not Applicable
Inhalation	Transitory upper respiratory irritation or eye irritation.	Single & Repeated	Moderate	Irritation and soreness in throat and nose. In extreme exposures some congestion may occur. Inhalation of crystalline silica has been classified by IARC as carcinogenic for humans (Group1). Inhalation of crystalline silica is also a known cause of silicosis, a non-cancerous lung disease caused by excessive exposure to crystalline silica. Respirable dust from this product may contain up to 26 % free crystalline silica (Cristobalite) and up to 3 % crystalline silica (Quartz). As such it represents a risk to the respiratory system. Long term, unprotected exposure to dust levels in excess of the TLV or PEL may cause lung disease (silicosis).	Lung
Ingestion	Material is probably not harmful if swallowed	Not Applicable	Mild	Low order of toxicity is expected when material is ingested.	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?: Yes Group 1 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 = 3, 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.

13.Disposal Considerations

Regulations: Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations. Vacuum clean dust with equipment fitted with a HEPA filter. Use dust suppression such as water if sweeping is necessary. Sweep up spilled material and place in closed containers for disposal.
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: <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
<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
<u>Section 302 Extremely Hazardous Substances (TPQ)</u> : None
<u>EPA Toxic Substances Control Act (TSCA) Status</u> : All of the components of this product are listed on the TSCA inventory.
<u>U.S. State Regulations California Proposition 65</u> :
Warning: This product contains silica, crystalline (airborne particles of respirable size) which is known by the State of California to cause cancer.
<u>International Regulations</u> : Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.
<u>European Community Labeling</u> : Not a dangerous preparation.
<u>European Inventory of New and Existing Chemicals Substances (EINECS)</u> : This product is a medical device and not subject to chemical notification requirements.

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.