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

1. Identification			
Product Name SDS Code Number			
Mercury	560898		
Substance Identity	Date of Last Revision		
Mercury 11/13/15			
Manufacturer:	Address		
DENTSPLY Caulk	38 West Clarke Avenue		
	Milford DE 19963-1805		
	http://www.caulk.com http://www.dentsply.com		
Grades or Minor Variant Identities	Information Telephone Number		
NA	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)		
Product Use (for Canada)	Emergency Telephone Number		
NA	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)		

# 2. Hazard(s) Identification



May be Corrosive to Metals

Keep only in original container. Absorb spillage to prevent material damage. Store in corrosive resistant container, with a resistant inner liner.



560898

Danger Toxic if inhaled

Avoid breathing vapours. Use in a well ventilated area. IF INHALED: remove to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or Doctor if you feel unwell.



Danger May cause damage to kidneys and central nervous system through prolonger or repeated exposure

> Do not breathe vapours. Get medical advice if you feel unwell.

# 3 Composition/Information on Ingredients

5. Composition/information on ingredients			
Hazardous Components CAS Number Exposure Limits %			
Mercury	7439-97-6	0.025mg/M <sup>3</sup>	100

### Mercury is a chemical known to the State of California to cause birth defects or other reproductive harm.

4. First Aid Measures				
Routes of Exposure	First Aid Instructions	Immediate Medical Attention	Delayed Effects	
Eye	Get medical aid immediately. Do NOT let victim rub eyes or keep eyes closed. Extensive irrigation with water is required (at least 30 minutes).	Do NOT let victim rub eyes or keep eyes closed. Extensive irrigation with water is required (at least 30 minutes).	Not Applicable	
Skin	Get medical aid immediately. Immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse. Destroy contaminated shoes.	Immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse. Destroy contaminated shoes.	Not Applicable	
Inhalation	Get medical aid immediately. Remove from exposure and move to fresh air immediately. If	Remove from exposure and move to fresh air immediately. If breathing is difficult, give oxygen. Do NOT use mouth to mouth resuscitation. If	Not Applicable	

	breathing is difficult, give oxygen. Do NOT use mouth to mouth resuscitation. If breathing has ceased apply artificial respiration using oxygen and a suitable mechanical device such as a bag and a mask.	breathing has ceased apply artificial respiration using oxygen and a suitable mechanical device such as a bag and a mask.	
Ingestion	Do not induce vomiting. If victim is conscious and alert, give 2-4 cupfuls of milk or water. Never give anything my mouth to an unconscious person. Get medical aid immediately. Wash mouth out with water.	If victim is conscious and alert, give 2-4 cupfuls of milk or water. Never give anything my mouth to an unconscious person. Get medical aid immediately. Wash mouth out with water.	Not Applicable
Other: Antidote	Not Applicable	The use of d-Penicillamine as a chelating agent should be determined by qualified medical personnel. The use of Dimercaprol or BAL (British Anti-Lewisite) as a chelating agent should be determined by qualified medical personnel	Not Applicable
thus is used f		tion of Mercury in whole blood is a reasonable measure of the body-burded ortively. Persons with kidney disease, chronic respiratory disease, liver dise	

# 5. Fire and Explosion Data

Flashpoint Method: Not Applicable	Flammable (Explosive) Limits in Air	Autoignition Temperature: Not Applicable	Other: Not	
	LEL: Not Applicable UEL: Not Applicable	Product will not autoignite.	Applicable	
Flame Propagation or Burning Rate	Properties Contributing to Fire Intensity:	Flammability Classification: Not Applicable		
(for Solids): Not Applicable	Not Applicable			
Extinguishing Media: Water spray, carbon dioxide, foam, or dry chemical. Extinguishing Media to Avoid: Water with full jet.				
Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices. Mercury vapors and mercury oxides				
generated during fires involving this material are toxic; additionally, this element can be irritating to contaminated tissue. Therefore, this material				
represents a severe health hazard to firefighters. Mercury is not flammable, and is relatively stable (though it can react with many metals to form amalgams). Water				
can cause environmental damage. Dike and collect water used to fight fire. During a fire, thermal decomposition or combustion may generate irritating and toxic				
gases.				
Unusual Fire and Explosion Hazards	Incinient fire responders should wear eve protection	on Structural firefighters must wear Self-Contained Breat	hing	

Unusual Fire and Explosion Hazards: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Move fire-exposed containers if it can be done without risk to firefighters. Apply cooling water to sides of containers that are exposed to flame until well after fire is out. Decontaminate all equipment thoroughly after the conclusion of fire-fighters activities. If possible, if prevent run-off water from entering storm drains, bodies of water, or other environmentally sensitive areas.

# 6. Accidental Release Measures

Containment Techniques: For small spills, absorb spill with inert material, such as: sand, vermiculite, earth or other absorbent material and place into suitable container. Do not touch spilled material. Avoid runoff into storm sewers and ditches, which lead to waterways. Keep unnecessary people away. Isolate hazard area. Use Protective equipment as in section 8.

Spill/Leak Clean-up Procedures and Equipment: Clean up spill immediately, using protective equipment as in section 8. Do not touch spilled material. Stop leak if you can do it without risk. For small spills, take up with sand or other absorbent material and place into container for disposal. Keep unnecessary people away. Isolate hazard area. Provide ventilation.

Evacuation Procedures: Not Applicable Special Instructions: Not Applicable Reporting Requirements: Not Applicable

## 7. Handling and Storage

Handling Practices and Warnings: Always keep mercury stored in a sealed container away from heat. Store away from food and beverages. 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 cool dry area. Store away from food and beverages. Minimize dust generation and accumulation. Avoid breathing dust and contact with eyes. Observe normal warehouse handling procedures. The avoidance of any air contaminant is always a recommended practice.

# 8. Exposure Control / Personal Protection



Ventilation: Ensur	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, resistant to the product and prevent skin exposure. Neoprene gloves are acceptable for routine use.		Not Applicable
Inhalation	Use sufficient natural or mechanical ventilation to keep vapor exposure level below	v PEL.	Not Applicable
Body Protection Protective work clothing such as lab coat to prevent skin exposure.			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. 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 Applicabl			nd Equipment: Not Applicable

## 9. Physical and Chemical Characteristics

Appearance: Silver liquid.	Odor: None
Normal Physical State: Metallic liquid.	Melting Point: -39°C (-38°F)

Specific Gravity: 13.6 g/cm <sup>3</sup>	Solubility in Water: Not soluble	pH: Not Applicable
Vapor Pressure (mm Hg): 0.002 mm Hg @ 25°C	Vapor Density: 6.9 (AIR=1)	Evaporation Rate (Butyl Acetate =1 Not Applicable
Other: Not Applicable		

#### **10. Stability and Reactivity Data**

Incompatibility (Materials to Avoid): Strong oxidizing materials. Oxygen, Sulfur, acetylene, ammonia, chlorine dioxide, azides, chlorates, nitrates, sulfuric acid, halogens, Rubidium, Calcium, 3-bromopropyne, ethylene oxide, Lithium, methylsilane + oxygen, peroxyformic acid, tetracarbonylnickel +oxygen, Copper alloys, boron diiodophosphide, metals, nitromethane, sodium carbide, Aluminum, Lead, Iron, and metal oxides. Hazardous Products Produced During Decomposition: Mercury vapors and mercury oxides generated during fires involving this material are toxic; additionally, this element can be irritating to contaminated tissue. Therefore, this material represents a severe health hazard to firefighters. Mercury is not flammable, and is relatively stable (though it can react with many metals to form amalgams). Hazardous Polymerization: May Occur May Not Occur Conditions to Avoid: Excessive heat. Material will readily vaporize. 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:

Carcinogenicity: NTP?: Not listed IARC monographs?: No OSHA regulated?: No.

Epidemiology: Intraperitoneal, rat: TDLo=400mg/Kg/14D-I (Tumorigenic-equivocal tumorigenic agent by RTECS criteria – tumors at site of application. Teratogenicity: Inhalation, rat: TCLo = 1mg/M3/24Hr (female 1-20days after conception) Effects on Embryo or Fetus – fetotoxicity (except death, e.g. stunted fetus).

Reproductive Effects: Inhalation, rat: TCLo = 890 ng/M3/24Hr (male 16 pre-mating) Paternal Effects – spermatogenesis (including genetic material, sperm morphology, motility, and count. Inhalation, rat: TCLo = 7440 ng/M3/24 Hr (male 16 weeks pre-mating) Fertility- post-implantation mortality (e.g. dead and/or resorbed implants per total numbers of implants).

Mutagenicity: Cytogenetic Analysis: Unreported, man =  $150 \mu g/M3$ .

Neurotoxicity: The brain is the critical organ in humans for chronic vapor exposure; in severe cases, spontaneous degeneration of the brain cortex can occur as a late sequela to past exposure.

## **12.Ecological Information**



Danger Very Toxic to aquatic life with long lasting effects

Avoid release to the environment Collect spillage

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Mercury is Toxic and Dangerous to the Environment. Do not allow Mercury to be released into streams or waterways.

EcoToxicity: Fish: Rainbow Trout  $LC_{50}$ = 0.16-0.90 mg/L; 96 Hr; Unspecified Fish: Bluegill/Sunfish:  $LC_{50}$ = 0.16-0.90 mg/L; 96 Hr; Unspecified Fish: Channel catfish:  $LC_{50}$ = 0.35 mg/L; 96 Hr; Unspecified Water Flea Daphnia:  $EC_{50}$ = 0.01 mg/L; 48 Hr; Unspecified. In aquatic systems, mercury appears to bind to dissolved matter or fine particulates, while the transport of mercury bound to dust particles in the atmosphere or bed sediments in rivers and lakes is generally less substantial. The conversion, in aquatic environments, of inorganic elemental mercury to methyl mercury implies that recycling of mercury from sediment to water to air and back could be a rapid process.

Environmental: Mercury bioaccumulates and concentrates in food chain (concentration may be as much as 10,000 times that of water). Bioconcentration factors of 63,000 for freshwater fish and 10,000 for saltwater fish have been found. Much of the mercury deposited on land appears to revaporize within a day or two, at least in areas substantially heated by sunlight.

Physical: All forms of mercury (metal, vapor, inorganic, or organic) are converted to methyl mercury. Inorganic forms are converted by microbial action in the atmosphere to methyl mercury.

## **13.Disposal Considerations**

Regulations: Do not incinerate or place in landfills, return to reclamation centers. Mercury may be salvaged or reclaimed for reuse. Dispose of in accordance with Federal, State and Local regulations.

RCRA P - Series Hazardous Waste Code: None Listed

RCRA U-Series Hazardous Waste Code for Mercury: U151



Properties (Physical/Chemical) Affecting Disposal:				
Regulated for Shipping: Yes DOT Shipping Name: Mercury contained in manufactured articles		Packing Group: III		
Do Changes in Quantities, packaging, or shipment method change product classification? DOT Hazard Class: 8		UN Number: 3506		
Yes, Over 1 pound RQ – Reportable Quantity				
DOT Labels Required (49CFR172.101): Yes, Over 1 pound RQ - Reportable Quantity, Corr	Other: Not Applicable			
IATA Shipping Name: Mercury contained in manufactured articles	IATA Hazard Class: 8	UN Number: 3506		
	Sub Risk 6.1			
IATA Hazard Labels Required: Reportable Quantity, Corrosive Label				
IMDG Shipping Name: Mercury contained in manufactured articles	IMDG Hazard Class: 8	UN Number: 3506		
IMDG Hazard Labels Required: Yes, Over 1 pound RQ – Reportable Quantity, Corrosive Label				

# **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: RQ is 1 pound for Mercury. Report spills required under federal, state and local regulations
EPCRA 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): Mercury. The Reportable Quantity RQ is 1 pound for Mercury.
EPCRA Section 302 Extremely Hazardous Substances EHS (TPQ): None
Clean Air Act section 112r: Mercury is considered as a hazardous air pollutant. (HAP).
Clean Water Act: Mercury is not listed as a Hazardous Substance under the CWA. Mercury is listed as a Priority Pollutant under the CWA. Mercury is listed as a
Toxic Pollutant under the CWA.
OSHA: OSHA does not consider Mercury highly hazardous.
<u>RCRA P – Series Hazardous Waste Code:</u> None Listed
RCRA U-Series Hazardous Waste Code for Mercury: U151
EPA Toxic Substances Control Act (TSCA) Status: Mercury (CAS# 7439-97-6) is listed on the TSCA inventory.
State Regulations: Mercury is on the following states Right to Know lists: California, New Jersey, Pennsylvania, Minnesota, and Massachusetts.
U.S. State Regulations California Proposition 65:
This product contains mercury, a chemical known to the State of California to cause birth defects or other reproductive harm.
Canada – DSL/NDSL: Mercury is listed on Canada's DSL List.
Canada – WHMIS: Mercury has a WHNIS classification of D2A, E. This chemical has been classified in accordance with the hazard criteria of the Controlled
Products Regulations and this MSDS contains all of the information required by those regulations.
Canada Ingredient Disclosure List: Mercury is listed on the Canadian Ingredient Disclosure List.
Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.
European Community Labeling: EC# 231-106-7 for Mercury. Mercury is Toxic and Dangerous for the Environment. R23 Toxic by Inhalation, R33 Danger of
Cumulative Effects. R50/R53 Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment. S1/2 Keep locked up and out of
reach of children, S7 Keep container tightly closed, S45 In case of accident or if you feel unwell, seek medical advice immediately (show label where possible),
S60 This material and its container must be disposed of as hazardous waste. S61 Avoid release to the environment. Refer to special instructions on the MSDS.
European Inventory of New and Existing Chemicals Substances (EINECS): EC# 231-106-7 for Mercury.
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.

# DENTSPLY Milford Safety Data Sheet

#### 1. Identification

Product Name	SDS Code Number
Dispersalloy <sup>®</sup>	556898
Substance Identity	Date of Last Revision
Dispersalloy <sup>®</sup> Dispersed Phase Alloy (Tablets & Powder)	04/18/16
Manufacturer:	Address
DENTSPLY Milford	38 West Clarke Avenue
	Milford DE 19963-1805
	http://www.dentsply.com
Grades or Minor Variant Identities	Information Telephone Number
Fast Set and Regular Set 1, 2, or 3 Spill	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)
Product Use (for Canada)	Emergency Telephone Number
Dental Amalgam Filling Material	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)

# 2. Hazard(s) Identification

Warning

May be harmful if swallowed.

Call a Poison Center or Physician if you feel unwell.

#### **3.** Composition/Information on Ingredients

Hazardous Components	EC Number	C.A.S. Number	Exposure Limits	%
Silver	231-131-3	7440-22-4	$0.1 \text{ mg/M}^3$	70
Tin	231-141-8	7440-31-5	$2 \text{ mg/M}^3$	18
Copper	231-159-6	7440-50-8	$1 \text{ mg/M}^3$	12

### 4. First Aid Measures

Routes of	First Aid Instructions	Immediate Medical	Delayed Effects
Exposure		Attention	
Eye	Immediately flush eyes with copious amounts	Not Applicable	Not Applicable
	of water for 15 minutes. Seek medical attention		
	if irritation or discomfort persists.		
Skin	Wash thoroughly with soap and water.	Not Applicable	Not Applicable
Inhalation	Gently blow nose and irrigate with clean	Not Applicable	Not Applicable
	water. Consult physician if irritation persists.		
Ingestion	If swallowed consult physician.	Not Applicable	Ingestion of alloy may cause GI tract irritation, nausea or diarrhea.
			TOXICITY: $LD_{50} > 5000 mg/kg$ .
			Low order of toxicity is expected if material is ingested.
Other:	Not Applicable	Not Applicable	Not Applicable
Note to Phy	sicians (Treating, Testing and Monitoring): Treat	symptomatically	

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

### 5. Fire and Explosion Data

Flashpoint Method: Not Applicable	Flammable (Explosive) Limits in Air	Autoignition Temperature: Not Applicable.	Other: Not	
	LEL: Not Applicable UEL: Not Applicable	Product will not autoignite.	Applicable	
Flame Propagation or Burning Rate (for Solids):	Properties Contributing to Fire Intensity:	Flammability Classification: Not Applicable		
Not Applicable	Not Applicable			
Extinguishing Media: Use dry powder extinguishing media.		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: Large quantities of metal powder in air may cause a fire or explosion hazard due to dusting. Molten metal can ignite				

combustibles In common with most powdered materials; this product should be treated as a combustible dust in the finely divided and suspended state. No dangerous decomposition products known. In large quantities product may present an explosion hazard due to dusting.

### 6. Accidental Release Measures

Containment Techniques: Material is a grey metallic dry powder. Store only in the original package. 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 cool dry area. Store away from food and beverages.

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 cool dry area. Store away from food and beverages. Minimize dust generation and accumulation. Avoid breathing dust and contact with eyes. Observe normal warehouse handling procedures. The avoidance of any air contaminant is always a recommended practice.

## 8. Exposure Control / Personal Protection



Ventilation: Ensure adequate ventilation, by either natural or mechanical means to keep exposure levels 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, resistant to the product and prevent skin exposure.		Not Applicable
Inhalation	Use sufficient natural or mechanical ventilation to keep vapor exposure level below PEL.		Not Applicable
Body Protection	Protective work clothing such as lab coat to prevent skin exposure.		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. 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: Grey colored, dry metallic powder or may be formed into pellets.		Odor: None
Normal Physical State: Metallic powder or may be formed into pellets.		Melting Point: Approximately 970°C (1778°F)
Specific Gravity: 9.6 g/cm <sup>3</sup>	Solubility in Water: Not soluble	pH: Not Applicable
Vapor Pressure (mm Hg): Not Applicable	Vapor Density (AIR=1) Not Applicable	Evaporation Rate (Butyl Acetate =1) Not Applicable
Other: Not Applicable		

## 10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Strong mineral acids, hydrogen peroxide, acetylene, and ethylenimine.		
Hazardous Products Produced During Decomposition: None.		
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: Product not considered hazardous. TOXICITY: LD<sub>50</sub> >5000mg/kg.

## **12.Ecological Information**

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Product not considered hazardous.

## **13.Disposal Considerations**

Regulations: The product or individual components may be salvaged or reclaimed for reuse. Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations. Pick up powder by carefully sweeping, vacuuming or wet mopping spilled material into an acceptable closed waste container. Avoid generating airborne dust.

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

### **14.Transport Information**

Regulated for Shipping: No DOT Shipping Name: Not Regulated	Packing Group: Not Applicable	
Do Changes in Quantities, packaging, or shipment method change product	DOT Hazard Class:	UN Number:
classification? NO	Not Applicable	Not Applicable
DOT Labels Required (49CFR172.101): Not Applicable	Other: 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: None.

EPCRA 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.

EPCRA Section 302 Extremely Hazardous Substances EHS (TPQ): None

EPA Toxic Substances Control Act (TSCA) Status: All of the components are listed on the TSCA inventory.

U.S. State Regulations California Proposition 65: None

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.

European Community Labeling: Not Applicable.

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.