# DENTSPLY/International DENTSPLY/Caulk Safety Data Sheet

#### 1. Identification

| Product Name                       | SDS Code Number                                 |  |
|------------------------------------|---|--|
| CALIBRA <sup>®</sup> Try In Paste  | 507893  |  |
| Substance Identity                 | Date of Last Revision                           |  |
| CALIBRA <sup>®</sup> Try In Paste  | 02/21/14  |  |
| 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                    |  |
| Not Applicable                     | (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time) |  |
| Product Use (for Canada)           | Emergency Telephone Number                      |  |
| Not Applicable                     | (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time) |  |
|                                    |   |  |

# 2. Hazard(s) Identification

#### WARNING CAUSES MILD SKIN IRRITATION If irritation occurs: Get medical advice/attention

### 3. Composition/Information on Ingredients

| Hazardous Components   | C.A.S. Number | Exposure Limits     | %         |
|------------------------|---------------|---------------------|-----------|
| Glycerine              | 56-81-5       | $10 \text{ mg/M}^3$ | > than 70 |
| Amorphous Fumed Silica | 7631-86-9     | $2 \text{ mg/M}^3$  | < than 20 |
| Titanium Dioxide       | 13463-67-7    | $10 \text{ mg/M}^3$ | < than 2  |
|                        |               |                     |           |

Other Information: Colorants are inorganic iron oxides.

# 3. Hazard Identification

| Emergenc      | y Overview: Material may be i                                      | rritating to eyes. No       | significant hazards for | or emergency responses are ki  | nown.           |
|---------------|--|-----------------------------|-------------------------|--|-----------------|
| Routes of     | S. 10 /  | Single, Repeated, or        | Severity (Mild,         | Acute and Chronic Health   |                 |
| Exposure      | Signs and Symptoms   | Lifetime Exposure           | Moderate, Severe)       | Effect(s)  | Target Organ(s) |
| Eye           | Material may cause slight<br>transient (temporary) irritation.     | Single & Repeated           | Moderate                | Irritation and possible corneal<br>damage due to the fillers used in<br>the product. | Not Applicable  |
| Skin          | Material may be an irritant after repeated and prolonged exposure. | Repeated                    | Mild                    | Irritation or possible allergic response.  | Not Applicable  |
| Inhalation    | Vapors are minimal due to<br>physical properties.                  | Not Applicable              | Not Applicable          | Not Applicable   | Not Applicable  |
| Ingestion     | Material is probably not harmful<br>if swallowed                   | Not Applicable              | Mild                    | Not Applicable   | Not Applicable  |
| Other         | Not Applicable   | Not Applicable              | Not Applicable          | Not Applicable   | Not Applicable  |
| Medical Con   | ditions Aggravated by Exposure Oper                                | n sores and wounds of the   | skin.                   |  |                 |
| Carcinogenio  | city NTP?: Not listed  | IARC monographs?: 1         | Not listed OSHA regul   | ated?: No All components of this pro   | duct are in     |
| compliance v  | with the inventory listing Requirement                             | s of the U.S. Toxic Subs    | ances Control Act (TSCA | ) Chemical Substance Inventory.  |                 |
| Potential Env | vironmental Effects Do not allow to er                             | nter sewers/ surface or gro | ound water.             |  |                 |
| NFPA Hazar    | d Classification Ratings (Scale 0-4), H                            | Health = 1, Fire = 0, React | tivity = 0              |  |                 |

# 4. First Aid Measures

| Routes of       | First Aid Instructions   | Immediate Medical | Delayed Effects |
|-----------------|--|-------------------|-----------------|
| Exposure        |  | Attention         |                 |
| Eye             | Rinse opened eye for several minutes under running water.            | Not Applicable    | Not Applicable  |
|                 | If symptoms persist consult physician                                |                   |                 |
| Skin            | Immediately wash with soap and water and rinse thoroughly.           | Not Applicable    | Not Applicable  |
| Inhalation      | Supply fresh air, consult physician if symptoms persist.             | Not Applicable    | Not Applicable  |
| Ingestion       | If symptoms persist consult physician. Do not induce vomiting unless | Not Applicable    | Not Applicable  |
|                 | instructed to do so by medical personnel.                            |                   |                 |
| Other           | Not Applicable   | Not Applicable    | Not Applicable  |
| Note to Physici | ans (Treating, Testing and Monitoring): Treat symptomatically.       |                   |                 |

## 5. Fire and Explosion Data

|                                      |                           | 1                   |                           |            |
|--------------------------------------|---------------------------|---------------------|---------------------------|------------|
| Flashpoint Method: 390°F (199°C) for | Flammable (Explosive) Lin | mits in Air         | Autoignition Temperature: | Other: Not |
| Glycerine. Pensky-Martin Closed Cup  | LEL: Not Applicable       | UEL: Not Applicable | 698°F (370°C)             | Applicable |

| Flame Propagation or Burning Rate (for  | Properties Contributing to Fire Intensity: Not | Flammability Classification:               |           |
|---|--|--|-----------|
| Solids) Not Applicable  | Applicable                                     | Not Applicable                             |           |
| Extinguishing Media: CO <sub>2</sub> , Water fog or fine spray, foam, carbon dioxide or alcohol resistant foams (ATC Type).                             |  | Extinguishing Media to Avoid: Water w jet. | vith full |
| Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.                                     |  |  |           |
| Unusual Fire and Explosion Hazards: During a fire, smoke may contain glycerine in addition to unidentified toxic and/or irritating compounds. Hazardous |  |  |           |
| combustion products may include but not limited to aldehydes, carbon monoxide and carbon dioxide.   |  |  |           |

## 6. Accidental Release Measures

| Containment Techniques: Material is a high viscosity paste, but will flow somewhat. |  |  |
|---|--|--|
| Spill/Leak Clean-up Procedures and Equipment: We                                    | ear protective clothing and 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. Glycerine freezes at  $64^{\circ}F(18^{\circ}C)$ . Product should be kept above  $64^{\circ}F(18^{\circ}C)$  but less than  $130^{\circ}F(54^{\circ}C)$ .

## 8. Exposure Control / Personal Protection



| Individual Protection      | Personal Protective Equipment for Normal Use                           | Personal Protective Equipment for    |
|----------------------------|--|--------------------------------------|
| Measures                   |  | 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   | Not Applicable                       |
| Body Protection            | Protective work clothing   | Not Applicable                       |
| Occupational Exposure Limi | ts: Not Applicable   | Engineering Controls: Not Applicable |

## 9. Physical and Chemical Characteristics

| Appearance: Creamy viscous paste. Multiple shades.   |   | Odor: Mild odor.                         |
|--|---|--|
| Normal Physical State: High Viscosity Liquid (Paste) |   | Melting Point: Not Applicable            |
| Specific Gravity: 1.4 g/cm <sup>3</sup>              | Solubility in Water: Partially soluble. | pH: Not Applicable                       |
| Vapor Pressure (mm Hg): Not Applicable               | Vapor Density (AIR=1): Not Applicable   | Evaporation Rate (Butyl Acetate =1): N A |
| Flashpoint Method: Not Applicable                    | Flammable (Explosive) Limits in Air     | Autoignition Temperature: Not Applicable |
|  | LEL: Not Applicable UEL: Not Applicable |  |
| Other: Not Applicable                                |   |  |

# 10. Stability and Reactivity Data

|   | ,                               |
|---|---------------------------------|
| Incompatibility (Materials to Avoid): Strong Oxidizing materials such as Sodium Hypochlorite or Hypochlorous Acid |                                 |
| Hazardous Products Produced During Decomposition: Acrolein.   |                                 |
| 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, Carcinogenicit                               | y, Neurological Effects,  | Genetic Effects, Reproduc      | tive Effects, or Structure Activity Dat  | a:              |
|------------------|--|---------------------------|--------------------------------|--|-----------------|
| For ingestion, t | he LD <sub>50</sub> for glycerine in Rats is 17,000                | ) – 27,000 mg/Kg.         |                                | -  |                 |
| Emergency Ov     | erview: Material may be mildly irritat                             | ing to eyes.              |                                |  |                 |
| Routes of        |  | Single, Repeated, or      | Severity (Mild, Moderate,      | Acute and Chronic Health   |                 |
| Exposure         | Signs and Symptoms   | Lifetime Exposure         | Severe)                        | Effect(s)  | Target Organ(s) |
| Eye              | Material may cause slight transient (temporary) irritation.        | Single & Repeated         | Moderate                       | Irritation and possible corneal<br>damage due to the fillers used in<br>the product. | Not Applicable  |
| Skin             | Material may be an irritant after repeated and prolonged exposure. | Repeated                  | Mild                           | Irritation or possible allergic response.  | Not Applicable  |
| Inhalation       | Vapors are minimal due to<br>physical properties.                  | Not Applicable            | Not Applicable                 | Not Applicable   | Not Applicable  |
| Ingestion        | Material is probably not harmful<br>if swallowed                   | Not Applicable            | Mild                           | Not Applicable   | Not Applicable  |
| Other            | Not Applicable   | Not Applicable            | Not Applicable                 | Not Applicable   | Not Applicable  |
| Medical Condit   | tions Aggravated by Exposure Open so                               | ores and wounds of the    | skin.                          |  |                 |
| Carcinogenicity  |  | IARC monographs?: N       |                                | ed?: No All components of this produ   | ict are in      |
|                  | h the inventory listing Requirements of                            |                           |                                |  |                 |
| Potential Envir  | onmental Effects: Potential Environme                              | ental Effects Do not allo | ow to enter sewers/ surface of | or ground water.   |                 |

## **12.Ecological Information**

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class1 (Selfassessment): 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. 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 | DOT Hazard Class: Not Applicable | UN Number: Not Applicable     |
| method change product classification? No         |                                  |                               |

## **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

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

<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> 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.

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.

# DENTSPLY/International DENTSPLY/Caulk Safety Data Sheet

#### 1. Identification

| 1. Iuchthication                           |   |  |  |  |
|--|---|--|--|--|
| Product Name                               | SDS Code Number                                 |  |  |  |
| CALIBRA®                                   | 507895  |  |  |  |
| Substance Identity                         | Date of Last Revision                           |  |  |  |
| CALIBRA <sup>®</sup> Esthetic Resin Cement | 05/16/13  |  |  |  |
| 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                    |  |  |  |
| Not Applicable                             | (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time) |  |  |  |
| Product Use (for Canada)                   | Emergency Telephone Number                      |  |  |  |
| Dual Curing Dental Crown and Bridge Cement | (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time) |  |  |  |

## 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     | %         |
|--|---------------------|---------------------|-----------|
| Barium boron fluoro alumino silicate glass | 65997-18-4          | $10 \text{ mg/m}^3$ | < than 70 |
| Bis-GMA                                    | 1565-94-2           | Not Established     | < than 20 |
| Polymerizable dimethacrylate resins        | 24448-20-2/109-16-0 | Not Established     | < than 15 |
| Hydrophobic Amorphous Silica               | 67762-90-7          | $3 \text{ mg/m}^3$  | < than 5  |

Other Information: Colorants are inorganic iron oxides and titanium dioxide.

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

| Hazardous Components                       | C.A.S. Number       | Exposure Limits     | %         |
|--|---------------------|---------------------|-----------|
| Barium boron fluoro alumino silicate glass | 65997-18-4          | $10 \text{ mg/m}^3$ | < than 70 |
| Bis-GMA                                    | 1565-94-2           | Not Established     | < than 20 |
| Polymerizable dimethacrylate resins        | 24448-20-2/109-16-0 | Not Established     | < than 15 |
| Hydrophobic Amorphous Silica               | 67762-90-7          | $3 \text{ mg/m}^3$  | < than 5  |
| Benzoyl peroxide                           | 94-36-0             | $5 \text{ mg/m}^3$  | < than 5  |

## 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. | Not Applicable              | Not Applicable  |  |  |
|   | If symptoms persist consult physician                     |                             |                 |  |  |
| Skin  | Immediately wash with soap and water and rinse thoroughly | Not Applicable              | Not Applicable  |  |  |
| Inhalation  | Not Applicable  | Not Applicable              | Not Applicable  |  |  |
| Ingestion   | Not Applicable  | Not Applicable              | Not Applicable  |  |  |
| Mucosa  | Rinse tissue for several minutes under running water.     | Not Applicable              | Not Applicable  |  |  |
|   | If symptoms persist consult physician                     |                             | -               |  |  |
| Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically. |   |                             |                 |  |  |

## **5. Fire Fighting Measures**

| Flame Propagation or Burning Rate  | Properties Contributing to Fire Intensity | Flammability Classification: Not Applicable | Other: Not Applicable |  |
|--|---|---|-----------------------|--|
| (for Solids) Not Applicable  | Not Applicable                            |   |                       |  |
| Extinguishing Media: CO <sub>2</sub> , extinguishing powder, foam carbon dioxide or water Extinguishing Media to Avoid: Water with full jet. |   |   |                       |  |
| spray. Fight larger fires with water spray or alcohol resistant foam.  |   |   |                       |  |
| Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.                          |   |   |                       |  |
| Unusual Fire and Explosion Hazards: Formation of toxic, irritating gases is possible from the decomposition of the dimethacrylate resins.    |   |   |                       |  |

Product does not present an explosion hazard.

# 6. Accidental Release Measures

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

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 contact dermatitis to susceptible persons. Ensure adequate ventilation.

 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

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 away from food and beverages.

# 8. Exposure Control / Personal Protection



| Occupational Exposure Limits: Not Applicable |  |                |  |  |  |  |
|--|--|----------------|--|--|--|--|
| Engineering Controls: No                     | Engineering Controls: Not Applicable   |                |  |  |  |  |
| Individual Protection                        | dual Protection Personal Protective Equipment for Normal Use Personal Protective Equipment for Emergencies |                |  |  |  |  |
| Measures                                     | 1 1  |                |  |  |  |  |
| Eye/Face                                     | Safety Glasses Not Applicable  |                |  |  |  |  |
| Skin   | The glove material has to be impermeable and Not Applicable  |                |  |  |  |  |
| resistant to the product.                    |  |                |  |  |  |  |
| Inhalation                                   | Not Required   | Not Applicable |  |  |  |  |
| Body Protection                              | Protective work clothing   | Not Applicable |  |  |  |  |

### 9. Physical and Chemical Characteristics

| Appearance: Creamy viscous paste. Multiple shades. |                                       | Odor: Characteristic sweet acrylic ester odor.      |
|--|---------------------------------------|---|
| Normal Physical State: High Viscosity Liquid (     | (Paste)                               | Melting Point: Not Applicable                       |
| Specific Gravity: 1.8 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 |
| Flashpoint Method: Not Applicable                  | Flammable (Explosive) Limits in Air   | Autoignition Temperature: Not Applicable,           |
| LEL: Not Applicable UEL: Not Applicable            |                                       | Product will not autoignite.                        |
|  |                                       |   |

Other: Not Applicable

## 10. Stability and Reactivity Data

| Incompatibility (Materials to Avoid): Strong Oxidizing materials.  |                                 |  |  |
|--|---------------------------------|--|--|
| Hazardous Products Produced During Decomposition: No dangerous decomposition products known if used according to Directions for Use. |                                 |  |  |
| 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 is an irritant to the skin and mucous membranes. The unpolymerized product may be an irritant to the skin in susceptible persons. On the eye the product has an irritating effect. Sensitization: Repeated or prolonged contact with the unpolymerized material may cause sensitization for persons allergic to acrylates and methacrylates. This product shows the following dangers according to internally approved calculation methods for composite materials: Irritant. Emergency Overview Material is irritating to eyes, respiratory system and skin.

| Routes of  |   | Single, Repeated, or | Severity (Mild,   | Acute and Chronic Health Effect(s)   | Target Organ(s) |
|------------|---|----------------------|-------------------|--|-----------------|
| Exposure   | Signs and Symptoms  | Lifetime Exposure    | Moderate, Severe) |  | 8 8 9           |
| Eye        | Material can cause<br>irritation.   | Single               | Moderate          | Irritation and possible corneal damage   | Not Applicable  |
| Skin       | Material may be an<br>irritant  | Single & Repeated    | Moderate          | Irritation or possible allergic response.<br>Severe allergic response may result in<br>breathing difficulties. | Not Applicable  |
| Inhalation | Not Applicable  | Not Applicable       | Not Applicable    | Not Applicable   | Not Applicable  |
| Ingestion  | Material is not harmful if<br>swallowed using clinically<br>relevant quantities | Not Applicable       | Mild              | Not Applicable   | Not Applicable  |

| Mucosa  | Material can cause   | Single | Mild | Inflammation of the mucosa | Not Applicable |
|---|--|--------|------|----------------------------|----------------|
|   | irritation.  |        |      |                            |                |
|   | 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 (Selfassessment): 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. 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 | DOT Hazard Class: Not Applicable | UN Number: Not Applicable     |
| method change product classification? No         |                                  |                               |

## **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.   |
| 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   |

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.