# **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                                    | SDS Code Number                                 |
|---|---|
| DYCAL® Radiopaque Calcium Hydroxide Composition | 523899  |
| Substance Identity                              | Date of Last Revision                           |
| DYCAL® Radiopaque Calcium Hydroxide Composition | 04/15/11  |
| 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 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     | $5 \text{ mg/M}^3$  | < than 20 |
| Zinc Oxide                                | 1314-13-2     | $10 \text{ mg/M}^3$ | < 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     | $5 \text{ mg/M}^3$  | < than 55 |
| Zinc Oxide           | 1314-13-2     | $10 \text{ mg/M}^3$ | < than 15 |
| Titanium Dioxide     | 13463-67-7    | $10 \text{ mg/M}^3$ | < than 10 |

## 3. Hazard Identification

| Emergency   | Emergency Overview: Material is an irritant. |                      |                   |   |                 |  |
|---|--|----------------------|-------------------|---|-----------------|--|
| Routes of   |  | 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 irritation.               | Single & Repeated    | Moderate          | Irritation and possible corneal                                     | Not Applicable  |  |
|   |  |                      |                   | damage due to the caustic nature of ingredient used in the product. |                 |  |
| Skin  | Material may cause irritation.               | Single & Repeated    | Mild              | Irritation or possible allergic                                     | Not Applicable  |  |
|   |  |                      |                   | response.   |                 |  |
| Inhalation  | Not Applicable                               | Not Applicable       | Not Applicable    | Not Applicable  | Not Applicable  |  |
| Ingestion   | Material may cause irritation.               | Not Applicable       | Mild              | Irritation due to the caustic                                       | Not Applicable  |  |
|   |  |                      |                   | nature of ingredients used in the                                   |                 |  |
|   |  |                      |                   | product.  |                 |  |
| 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       | 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, If symptoms persist consult physician.                      | Not Applicable    | Not Applicable  |  |  |
|                 | This may not be of concern when using clinically relevant quantities.         |                   |                 |  |  |
| Ingestion       | Rinse out mouth and then drink plenty of water. Consult a physician           | Not Applicable    | Not Applicable  |  |  |
|                 | immediately.  |                   |                 |  |  |
|                 | This may not be of concern when using clinically relevant quantities.         |                   |                 |  |  |
| Other           | Not Applicable  | Not Applicable    | Not Applicable  |  |  |
| Note to Physici | Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically. |                   |                 |  |  |

5. Fire and Explosion Data

| 5. The and Explosion Data   |   |                              |            |  |  |
|---|---|------------------------------|------------|--|--|
| Flashpoint Method: Not Applicable   | Flammable (Explosive) Limits in Air                       | Autoignition Temperature:    | Other: Not |  |  |
|   | LEL: Not Applicable UEL: Not Applicable                   | Not Applicable               | Applicable |  |  |
| Flame Propagation or Burning Rate (for Solids):   | Properties Contributing to Fire Intensity: Not Applicable | Flammability Classification: |            |  |  |
| Not Applicable  |   | Not Applicable               |            |  |  |
| Extinguishing Media: Use fire extinguishing methods suitable to surrounding conditions.  Extinguishing Media to Avoid: Not Applicab |   |                              |            |  |  |
| 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     | 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. This may not be of concern when using clinically relevant quantities. | Not Applicable                    |
| Body Protection           | Protective work clothing  | Not Applicable                    |
| Occupational Exposure Lim | 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        | pH: Base-Not Applicable, Catalyst- 11.5             |
| Vapor Pressure (mm Hg): 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 |   |
| Other: Not Applicable   |   |   |

# 10. Stability and Reactivity Data

| Incompatibility (Materials to Avoid): Not Applicable         |                                 |
|--|---------------------------------|
| Hazardous Products Produced During Decomposition: Not Applie | eable                           |
| 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:

| Irritating to skir  | Irritating to skin and mucous membranes. |                      |                           |                                      |                 |  |
|---|--|----------------------|---------------------------|--------------------------------------|-----------------|--|
| Emergency Ove   | erview: Material is an irritant.         |                      |                           |                                      |                 |  |
| 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 irritation.           | Single & Repeated    | Moderate                  | Irritation and possible corneal      | Not Applicable  |  |
|   |  |                      |                           | damage due to the caustic nature     |                 |  |
|   |  |                      |                           | of ingredient used in the product.   |                 |  |
| Skin  | Material may cause irritation.           | Single & Repeated    | Mild                      | Irritation or possible allergic      | Not Applicable  |  |
|   |  |                      |                           | response.                            |                 |  |
| 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 | Not Applicable  |  |
|   |  |                      |                           | of ingredients used in the product.  |                 |  |
| Other   | Not Applicable                           | Not Applicable       | Not Applicable            | Not Applicable                       | Not Applicable  |  |
| Medical Conditions Aggregated by Exposure Open seres and wounds of the skin |  |                      |                           |                                      |                 |  |

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 | 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

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 Incase 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.



# DENTSPLY/International DENTSPLY/Caulk Safety Data Sheet

523899

### 1. Identification

| Product Name                                    | SDS Code Number                                 |
|---|---|
| DYCAL® Radiopaque Calcium Hydroxide Composition | 523899  |
| Substance Identity                              | Date of Last Revision                           |
| DYCAL® Radiopaque Calcium Hydroxide Composition | 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 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     | $5 \text{ mg/M}^3$  | < than 20 |
| Zinc Oxide                                | 1314-13-2     | $10 \text{ mg/M}^3$ | < 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     | $5 \text{ mg/M}^3$  | < than 55 |
| Zinc Oxide           | 1314-13-2     | $10 \text{ mg/M}^3$ | < than 15 |
| Titanium Dioxide     | 13463-67-7    | $10 \text{ mg/M}^3$ | < than 10 |

## 3. Hazard Identification

| Emergency Overview: Material is an irritant.  |  |                      |                   |   |                 |
|---|--|----------------------|-------------------|---|-----------------|
| Routes of   |  | 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 irritation.   | Single & Repeated    | Moderate          | Irritation and possible corneal                                     | Not Applicable  |
|   |  |                      |                   | damage due to the caustic nature of ingredient used in the product. |                 |
| Skin  | Material may cause irritation.   | Single & Repeated    | Mild              | Irritation or possible allergic                                     | Not Applicable  |
|   |  |                      |                   | response.   |                 |
| Inhalation  | Not Applicable   | Not Applicable       | Not Applicable    | Not Applicable  | Not Applicable  |
| Ingestion   | Material may cause irritation.   | Not Applicable       | Mild              | Irritation due to the caustic                                       | Not Applicable  |
|   |  |                      |                   | nature of ingredients used in the                                   |                 |
|   |  |                      |                   | product.  |                 |
| Other   | Other Not Applicable Not Applicable Not Applicable Not Applicable Not Applicable |                      |                   |   | Not Applicable  |
| Medical Con   | 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       | 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, If symptoms persist consult physician.              | Not Applicable    | Not Applicable  |
|                 | This may not be of concern when using clinically relevant quantities. |                   |                 |
| Ingestion       | Rinse out mouth and then drink plenty of water. Consult a physician   | Not Applicable    | Not Applicable  |
|                 | immediately.  |                   |                 |
|                 | This may not be of concern when using clinically relevant quantities. |                   |                 |
| Other           | Not Applicable  | Not Applicable    | Not Applicable  |
| Note to Physici | ans (Treating, Testing and Monitoring): Treat symptomatically.        | -                 | ·               |

5. Fire and Explosion Data

| 5.1 He and Explosion Data  |   |                              |                |
|--|---|------------------------------|----------------|
| Flashpoint Method: Not Applicable  | Flammable (Explosive) Limits in Air                       | Autoignition Temperature:    | Other: Not     |
|  | LEL: Not Applicable UEL: Not Applicable                   | Not Applicable               | Applicable     |
| Flame Propagation or Burning Rate (for Solids):  | Properties Contributing to Fire Intensity: Not Applicable | Flammability Classification: | 1              |
| Not Applicable   |   | Not Applicable               |                |
| Extinguishing Media: Use fire extinguishing methods suitable to surrounding conditions.  Extinguishing Media to Avoid: Not Applicable to Surrounding Conditions. |   |                              | lot 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     | 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. This may not be of concern when using clinically relevant quantities. | Not Applicable                       |
| Body Protection           | Protective work clothing  | Not Applicable                       |
| Occupational Exposure Lim | its: Not Applicable   | Engineering Controls: Not Applicable |

# 9. Physical and Chemical Characteristics

|   | v                                       |   |
|---|---|---|
| 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        | pH: Base-Not Applicable, Catalyst- 11.5             |
| 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 |   |
| Other: Not Applicable   |   |   |

# 10. Stability and Reactivity Data

| Incompatibility (Materials to Avoid): Not Applicable             |                                 |  |
|--|---------------------------------|--|
| Hazardous Products Produced During Decomposition: Not Applicable |                                 |  |
| 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:

| Irritating to skin and mucous membranes.                                     |                                |                      |                           |                                      |                 |  |  |
|--|--------------------------------|----------------------|---------------------------|--------------------------------------|-----------------|--|--|
| Emergency Overview: Material is an irritant.                                 |                                |                      |                           |                                      |                 |  |  |
| 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 irritation. | Single & Repeated    | Moderate                  | Irritation and possible corneal      | Not Applicable  |  |  |
|  |                                |                      |                           | damage due to the caustic nature     |                 |  |  |
|  |                                |                      |                           | of ingredient used in the product.   |                 |  |  |
| Skin   | Material may cause irritation. | Single & Repeated    | Mild                      | Irritation or possible allergic      | Not Applicable  |  |  |
|  |                                |                      |                           | response.                            |                 |  |  |
| 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 | Not Applicable  |  |  |
|  |                                |                      |                           | of ingredients used in the product.  |                 |  |  |
| Other  | Not Applicable                 | Not Applicable       | Not Applicable            | Not Applicable                       | Not Applicable  |  |  |
| Medical Conditions Aggregated by Evnogues Open gares and grounds of the skip |                                |                      |                           |                                      |                 |  |  |

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 | 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

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 Incase 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.