# **SAFETY DATA SHEETS**

# This SDS packet was issued with item:

071806165

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

071806199 071806405 071806538

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).

071806082 071806090 071806413 071806421 071806439 071806447 071806546 071806553 071806561 071806579 071806744 071807403 071807494

# DENTSPLY/International DENTSPLY/Caulk Safety Data Sheet

578617

### 1. Identification

| Product Name  | SDS Code Number                                 |
|---|---|
| Aquasil   | 578617  |
| Substance Identity  | Date of Last Revision                           |
| Aquasil, Aquasil Ultra, Aquasil Ultra Xtra  | 02/02/11  |
| Smart Wetting <sup>®</sup> Impression Material  |   |
| Vinyl Polysiloxane Impression Material  |   |
| 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                    |
| AQUASIL MONOPHASE, AQUASIL RIGID, AQUASIL LV, AQUASIL Easy  | (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time) |
| Mix PUTTY, Smart Wetting® Impression Material, AQUASIL ULTRA  |   |
| MONOPHASE, AQUASIL ULTRA RIGID, AQUASIL ULTRA XLV, AQUASIL  |   |
| ULTRA LV, AQUASIL ULTRA HEAVY – Smart Wetting <sup>®</sup> Impression Material Fast Setting and Regular Setting – Including AQUASIL ULTRA DECA™ Smart |   |
| Wetting® Impression Material for Dynamic Mixing Machines and digit® Targeted  |   |
| Delivery Systems. AQUASIL ULTRA Xtra – Wash, Tray and DECA Tray.  |   |
| Product Use (for Canada)  | Emergency Telephone Number                      |
| Dental Impression Material  | (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time) |

# 2. Hazard(s) Identification



# WASH HANDS THOROUGHLY AFTER HANDLING WEAR PROTECTIVE GLOVES

IF ON SKIN: WASH WITH PLENTY OF SOAP AND WATER.
IF SKIN IRRITATION OCCURS: GET MEDICAL ADVICE / ATTENTION
TAKE OFF CONTAMINATED CLOTHING AND WASH BEFORE REUSE

3. Composition/Information on Ingredients

| Hazardous Components               | C.A.S. Number | Exposure Limits       | %         |
|------------------------------------|---------------|-----------------------|-----------|
| Silicon Dioxide -Crystalline       | 14464-46-1    | $0.05 \text{ mg/m}^3$ | < than 30 |
| Silicon Dioxide - Amorphous        | 68855-54-9    | $1.20 \text{ mg/m}^3$ | < than 30 |
| Hydrophobic Amorphous Fumed Silica | 68909-20-6    | $10 \text{ mg/m}^3$   | < than 10 |
| Titanium Dioxide                   | 13463-67-7    | $10 \text{ mg/m}^3$   | < than 5  |

<u>Colorant Information</u>: The base pastes may contain fluorescent organic dyes and/or ultramarine pigments and/or inorganic iron oxides. The base pastes may also contain a red pigment known as a Red 2B Toner or a Calcium salt of a beta oxynaphthoate. The Chemical structure of all Ultramarine pigments, regardless of color, is Sodium Aluminosulfosilicate.

<u>Odorant Information:</u> This product contains Peppermint oil which may cause irritation to skin or mucosa or other allergic responses in susceptible persons.

### 4. First Aid Measures

| Routes of  | First Aid Instructions                                       | Immediate         | Delayed Effects  |
|------------|--|-------------------|--|
| Exposure   |  | Medical Attention |  |
| Eye        | Rinse opened eye for several minutes under running water. If | Not Applicable    | Not Applicable   |
|            | 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                        | Not Applicable    | Low order of toxicity is expected when large           |
|            |  |                   | amounts of material are ingested. Acute                |
|            |  |                   | toxicology study in rats LD <sub>50</sub> >2,000mg/kg. |
| Other      | Not Applicable   | Not Applicable    | Not Applicable   |

|  | icians (Treating |  |  |
|--|------------------|--|--|
|  |                  |  |  |
|  |                  |  |  |
|  |                  |  |  |
|  |                  |  |  |

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. |   |  | et.   |                       |
| 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: No dangerous decomposition products known 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. |   |  |
| 1 | Avoid gross skin contact to minimize the possibility   | of contact dermatitis to susceptible persons. E | nsure 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 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   | Not Applicable                       |
| Body Protection                              | Protective work clothing   | Not Applicable                       |
| Occupational Exposure Limits: Not Applicable |  | Engineering Controls: Not Applicable |

# 9. Physical and Chemical Characteristics

| Appearance: Various colored pastes, may be high viscosity paste or runny. Catalyst is grey-colored.              |   | Odor: Characteristic sweet ester odor.    |
|--|---|---|
| Normal Physical State: Material is available in several viscosities. It varies from a very high viscosity liquid |   | Melting Point: Not Applicable             |
| (Paste) to a more runny material.  |   |   |
| Specific Gravity: Varies from 1.2 g/cm <sup>3</sup> to 1.5 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): N A  |
| 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 danger       | ous 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,   | Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data:        |                            |                   |   |                 |
|--|---|----------------------------|-------------------|---|-----------------|
| Product may irr  | Product may irritate the skin and mucous membranes. The unpolymerized product may cause irritation to the skin in susceptible persons. On the eye the |                            |                   |   |                 |
| product has an   | irritating effect. Sensitization: No  | o sensitizing effects know | vn.               |   |                 |
| Emergency Ove  | erview: Material may be mildly  | irritating to eyes.        |                   |   |                 |
| Routes of  |   | Single, Repeated, or       | Severity (Mild,   | Acute and Chronic Health Effect(s)              |                 |
| Exposure   | Signs and Symptoms  | Lifetime Exposure          | Moderate, Severe) |   | Target Organ(s) |
| Eye  | Material can cause irritation.  | Single                     | Moderate          | Irritation and possible corneal damage          | Not Applicable  |
| Skin   | Material may be an irritant   | Single & Repeated          | Moderate          | Irritation or possible allergic response.       | Not Applicable  |
| Inhalation   | Not Applicable  | Not Applicable             | Not Applicable    | Not Applicable                                  | Not Applicable  |
| Ingestion  | Material is probably not  | Not Applicable             | Mild              | Low order of toxicity is expected when          | Not Applicable  |
|  | harmful if swallowed  |                            |                   | large amounts of material are ingested.         |                 |
|  |   |                            |                   | Acute toxicology study in rats LD <sub>50</sub> |                 |
|  |   |                            |                   | >2,000mg/kg.                                    |                 |
| 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 | e inventory listing Requiren  | nents of the U. S. Toxic Substances Cont | rol Act (TSCA) Chemical Substance Inventory.              |
| Potential Environme | ental Effects Do not allow t  | o enter sewers/ surface or ground water. |   |
| NFPA Hazard Class   | sification Ratings (Scale 0-4 | 1). Health = 0. Fire = 1. Reactivity = 0 |   |

### 12. Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water streams or sewage system.

# 13.Disposal Considerations

| Regulations: 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.

LLS Federal Regulations: CERCLA 103 Reportable Quantity: This product is not subject to CERCLA reporting requirements.

U.S. Federal Regulations: <u>CERCLA 103 Reportable Quantity:</u> This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations

<u>Section 313 Toxic Chemicals:</u> This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None

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>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 Milford Safety Data Sheet

1. Product and Company Identification

| The state of the s |                         |
|--|-------------------------|
| Product Name   | SDS Code Number         |
| Aquasil®   | 578617                  |
| Substance Identity   | Date of Last Revision   |
| Aquasil, Aquasil Ultra, Aquasil Ultra Xtra, Smart Wetting® Impression Material, Aquasil  | 05/09/16                |
| Ultra Cordless Tissue Managing Impression Material, Aquasil Ultimate - Tissue  |                         |
| Managing Impression Material, Aquasil Ultra + Smart Wetting Impression Material  |                         |
| Manufacturer:  | Address                 |
| DENTSPLY Milford   | 38 West Clarke Avenue   |
|  | Milford DE 19963-1805   |
|  | http://www.dentsply.com |
| Grades or Minor Variant Identities   | Information Telephone   |
| AQUASIL MONOPHASE, AQUASIL RIGID, AQUASIL LV, AQUASIL Easy Mix PUTTY - Smart Wetting®  | Number: (302) 422-4511  |
| Impression Material, AQUASIL ULTRA MONOPHASE, AQUASIL ULTRA RIGID, AQUASIL ULTRA XLV, AQUASIL ULTRA LV, AQUASIL ULTRA HEAVY – Smart Wetting <sup>®</sup> Impression Material, Super Fast Set, Fast Setting   | (8:00 AM – 4:30 PM      |
| and Regular Setting – Including AQUASIL ULTRA DECA™ Smart Wetting® Impression Material for Dynamic Mixing  | Eastern Time)           |
| Machines and digit Targeted Delivery Systems. AQUASIL ULTRA Xtra – Wash, Tray and DECA Tray. Aquasil Ultra   | ,                       |
| Cordless Tissue Managing Wash Impression Material and Aquasil Ultra Cordless Tissue Managing Tray Impression   |                         |
| Material, Aquasil Ultimate Cordless Tissue Managing Wash Impression Material, Aquasil Ultra Cordless Tissue Managing Tray Impression Material, Aquasil Ultra + Smart Wetting Impression Material Fast and Regular Setting - all viscosities.   |                         |
| Product Use (for Canada)   | Emergency Telephone     |
| Dental Impression Material   | Number: (302) 422-4511  |
| Dental impression Material   | (8:00 AM – 4:30 PM      |
|  | Eastern Time)           |
|  | Lasterii Tiille)        |

# 2. Hazard(s) Identification



# 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

|                                    | 0             |                       |           |
|------------------------------------|---------------|-----------------------|-----------|
| Hazardous Components               | C.A.S. Number | Exposure Limits       | %         |
| Silicon Dioxide -Crystalline       | 14464-46-1    | $0.05 \text{ mg/m}^3$ | < than 30 |
| Silicon Dioxide - Amorphous        | 68855-54-9    | $1.20 \text{ mg/m}^3$ | < than 30 |
| Hydrophobic Amorphous Fumed Silica | 68909-20-6    | $10 \text{ mg/m}^3$   | < than 10 |
| Titanium Dioxide                   | 13463-67-7    | $10 \text{ mg/m}^3$   | < than 10 |

<u>Colorant Information</u>: The base pastes may contain fluorescent organic dyes and/or ultramarine pigments and/or inorganic iron oxides. The base pastes may also contain a red pigment known as a Red 2B Toner or a Calcium salt of a beta oxynaphthoate. The Chemical structure of all Ultramarine pigments, regardless of color, is Sodium Aluminosulfosilicate.

<u>Odorant Information:</u> This product contains Peppermint oil which may cause irritation to skin or mucosa or other allergic responses in susceptible persons.

### 4. First Aid Measures

|            | 17 1 11 57 11 11 11 11 11 11 11 11 11 11 11 11 11            |                   |  |  |  |  |
|------------|--|-------------------|--|--|--|--|
| Routes of  | First Aid Instructions                                       | Immediate         | Delayed Effects                              |  |  |  |
| Exposure   |  | Medical Attention |  |  |  |  |
| Eye        | Rinse opened eye for several minutes under running water. If | Not Applicable    | Not Applicable                               |  |  |  |
|            | 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                        | Not Applicable    | Low order of toxicity is expected when large |  |  |  |

|                 |  |                | amounts of material are ingested. Acute toxicology study in rats LD <sub>50</sub> >2,000mg/kg. |
|-----------------|--|----------------|--|
| Other           | Not Applicable   | Not Applicable | Not Applicable   |
| Note to Physici | ans (Treating, Testing and Monitoring): Treat symptomatically. |                |  |

5. Fire Fighting Measures

|   | 0 0                                      |  |                       |
|---|--|--|-----------------------|
| 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: CO2, extinguish  | ing powder, foam carbon dioxide or water | Extinguishing Media to Avoid: Water with full jo | et.                   |
| spray. Fight larger fires with water spr  | ray or alcohol resistant foam.           |  |                       |
| Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.         |  |  |                       |
| Unusual Fire and Explosion Hazards: No dangerous decomposition products known 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 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                  |  | Not Applicable                    |
| Body Protection Protective work clothing |  | Not Applicable                    |
| Occupational Exposure Lim                | Engineering Controls: Not Applicable                                   |                                   |

# 9. Physical and Chemical Characteristics

| Appearance: Various colored pastes, may be high viscosity                    | Odor: Peppermint odor.                |   |
|--|---------------------------------------|---|
| Normal Physical State: Material is available in several visc                 | Melting Point: Not Applicable         |   |
| (Paste) to a more runny material.  |                                       |   |
| Specific Gravity: Varies from 1.1 g/cm <sup>3</sup> to 1.5 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): N A  |
| Flashpoint Method: Not Applicable  | Flammable (Explosive) Limits in Air   | Autoignition Temperature: 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 may irritate the skin and mucous membranes. The unpolymerized product may cause irritation to the skin in susceptible persons. On the eye the product has an irritating effect. Sensitization: No sensitizing effects known.

| Emergency Ov | Emergency Overview: Material may be mildly irritating to eyes. |                      |                   |   |                 |
|--------------|--|----------------------|-------------------|---|-----------------|
| Routes of    |  | Single, Repeated, or | Severity (Mild,   | Acute and Chronic Health Effect(s)              |                 |
| Exposure     | Signs and Symptoms   | Lifetime Exposure    | Moderate, Severe) |   | Target Organ(s) |
| Eye          | Material can cause irritation.                                 | Single               | Moderate          | Irritation and possible corneal damage          | Not Applicable  |
| Skin         | Material may be an irritant                                    | Single & Repeated    | Moderate          | Irritation or possible allergic response.       | Not Applicable  |
| Inhalation   | Not Applicable   | Not Applicable       | Not Applicable    | Not Applicable                                  | Not Applicable  |
| Ingestion    | Material is probably not                                       | Not Applicable       | Mild              | Low order of toxicity is expected when          | Not Applicable  |
|              | harmful if swallowed   |                      |                   | large amounts of material are ingested.         |                 |
|              |  |                      |                   | Acute toxicology study in rats LD <sub>50</sub> |                 |

|   |                |                |                | >2,000mg/kg.   |                |
|---|----------------|----------------|----------------|----------------|----------------|
| Other   | 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 = 0, Fire = 1, Reactivity = 0  |                |                |                |                |                |

# 12. Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water streams or sewage system.

### 13.Disposal Considerations

Regulations: 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>U.S. State Regulations California Proposition 65:</u> This product does not contain any chemicals, which are on the California Proposition 65 list.

<u>International Regulations: Canadian Environmental Protection Act:</u>

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.