

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

072692705

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

070866798 072692721 072692739 072692747 072692754 072692762 072692770 072692788 072692796 072692804  
072692812 072692820 072692838 072692846 072692853 072692861 072692903 072692911 072722213 072722221  
072722239 072722247 072722254 072722262 072722288 072722296 072722304 072722312 072722320 072722338  
072722346 072722353 072722361 072722379 072722387 072722395 072722403 072722411 072722429 072722502  
072722569 072722577 072722585 072722593 072722601 072722619 072722627 072722635 072722643 072722700  
072722718 072722726 072722759 072722767 072722775 072722783 072722791 072722809 072722817 072722825  
072722833 072722841 072722858 072722866 072722874 072722908 072722916 072722924 072722932 072722940  
072722957 072722965 072722973 072722981 072722999 072723005 072723013 072723021 072723039 072723047

# DENTSPLY International

## DENTSPLY PROSTHETICS

### Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: 06 June 2013  
Document Number: 452  
Date Revised: 11 September 2013  
New

#### 1. PRODUCT IDENTIFICATION

**Trade Name (as labeled):** CELTRA™ Universal Overglaze, Universal Stain

**Product Identifier (Part/Item Number):** Overglaze: 601322; Stain: 601500-601505, 601511, 601512, 601520-601526

**U.N. Number:** Not Regulated

**U.N. Dangerous Goods Classification:** Not Regulated

**Recommended Use:** Used for staining and glazing CELTRA DUO and other lithium silicate based restorations and Cercon zirconia.

**Restrictions on Use:** For Professional Use Only

**Manufacturer/Supplier Name:** Dentsply Prosthetics

**Manufacturer/Supplier Address:** 570 West College Ave.  
York, PA 17405-0872

**Manufacturer/Supplier Telephone Number:** 717-845-7511 (Product Information)

**Emergency Contact Telephone Number:** 800-424-9300 Chemtrec

**Email address:** Prosthetics\_MSDS@Dentsply.com

#### 2. HAZARD(s) IDENTIFICATION

**EU Classification (1999/45/EC):** Not a dangerous preparation

**Refer to Section 16 for the full text of the EU Classifications and R Phrases.**

**Labeling in accordance with 1999/45/EC**

None Required

**US Hazard Classification:** Not Hazardous

#### 3. COMPOSITION AND INFORMATION ON INGREDIENTS

| Hazardous Components             | C.A.S. #    | EINECS #    | Substance Classification | WT %  |
|----------------------------------|-------------|-------------|--------------------------|-------|
| Sodium Potassium Aluminosilicate | Proprietary | Proprietary | Not Applicable           | 60-70 |

|                      |            |           |                |      |
|----------------------|------------|-----------|----------------|------|
| 1, 3 Butylene Glycol | 107-88-0   | 203-529-7 | Not Applicable | 0-18 |
| Di(propylene) Glycol | 25265-71-8 | 246-770-3 | Not Applicable | 0-12 |





The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS and H phrases and EU Classifications and R Phrases.

#### 4. FIRST-AID MEASURES





| Routes of Exposure  | First Aid Instructions   |
|---|--|
| Eye   | Flush victim's eyes with water, while holding the eyelids apart. Check victim for contact lenses and remove if possible while flushing. Get medical attention if irritation occurs and persists. |
| Skin  | Wash skin with plenty of water. Get medical attention if irritation develops or persists.  |
| Inhalation  | Remove victim to fresh air. Get medical attention if irritation develops.  |
| Ingestion   | If small quantities are swallowed, rinse out mouth with water. Do not induce vomiting. If irritation or discomfort occurs, get medical attention.  |
| Most important symptoms of exposure   | May cause eye irritation.  |
| Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically. Immediate medical attention should not be required. |  |

#### 5. FIRE-FIGHTING MEASURES

|   |  |  |   |
|---|--|--|---|
| <b>Suitable Extinguishing Media:</b>  | Use dry chemical, carbon dioxide, alcohol or polymer foam.   |  |   |
| <b>Fire Fighting Procedures:</b>  | Use water to cool fire-exposed containers.   |  |   |
| <b>Specific Hazards Arising from the Chemical:</b>                                  | Decomposition may release oxides of carbon and butadiene.  |  |   |
| <b>Precautions for Fire Fighters:</b>   | Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. |  |   |
| <b>Recommended Protective Equipment for Fire Fighters:</b>                          |  |  |   |
| <b>EYES/FACE</b>  | <b>HANDS</b>   | <b>RESPIRATORY</b>   | <b>THERMAL</b>  |
|  |                                   |  |  |

#### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, PPE and Emergency Procedures:** Evacuate spill area and keep unprotected personnel away. Ventilate area. Wear appropriate protective clothing as described in Section 8. Avoid contact with skin, eyes or clothing.

|  |   |  |   |
|--|---|--|---|
| Avoid breathing vapors.  |   |  |   |
| <b>Environmental Precautions:</b> Prevent entry into sewers and waterways. Report releases as required by local and national authorities.        |   |  |   |
| <b>Methods and Materials for Containment and Clean-up:</b> Promptly wipe up or scoop up spills and place in appropriate containers for disposal. |   |  |   |
| <b>Recommended Personal Protective Equipment for Containment and Clean-up:</b>   |   |  |   |
| <b>EYES/FACE</b>   | <b>HANDS</b>  | <b>RESPIRATORY</b>   | <b>SKIN</b>   |
|   |  |  |  |

## 7. HANDLING AND STORAGE

**Precautions for Safe Handling:** Avoid contact with the eyes, skin and clothing. Avoid breathing vapors. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use.



Do not reuse containers. Empty containers retain product residues and can be hazardous. Follow all SDS precautions when handling empty containers.

**Conditions for Safe Storage:** Store in a cool, dry, well-ventilated area away from incompatible materials. Keep container tightly closed.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Occupational Exposure Limits:

|                                  |               |                  |
|----------------------------------|---------------|------------------|
| Sodium Potassium Aluminosilicate | United States | None Established |
|----------------------------------|---------------|------------------|

|   |   |  |             |
|---|---|--|-------------|
|   | Germany   | None Established   |             |
|   | United Kingdom  | None Established   |             |
|   | European Union  | None Established   |             |
| 1, 3 Butylene glycol  | United States   | None Established   |             |
|   | Germany   | None Established   |             |
|   | United Kingdom  | None Established   |             |
|   | European Union  | None Established   |             |
| Di(propylene) Glycol  | United States   | None Established   |             |
|   | Germany   | 100 mg/m <sup>3</sup> (Inhalable, Sum of vapor and aerosol) TWA, 200 mg/m <sup>3</sup> STEL DFG MAK (Skin) |             |
|   | United Kingdom  | None Established   |             |
|   | European Union  | None Established   |             |
| <b>Biological Exposure Limits:</b> None Established.  |   |  |             |
| <b>Appropriate Engineering Controls:</b> Use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits.  |   |  |             |
| <b>Individual Protection Measures (PPE)</b><br><b>Specific Eye/face Protection:</b> Chemical safety glasses are recommended to avoid contact.<br><b>Specific Skin Protection:</b> No special protection is required.<br><b>Specific Respiratory Protection:</b> None should be needed for normal use. If the exposure limits are exceeded an approved organic vapor respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice.<br><b>Specific Thermal Hazards:</b> None required. |   |  |             |
| <b>Recommended Personal Protective Equipment</b>  |   |  |             |
| <b>EYES/FACE</b>  | <b>HANDS</b>  | <b>RESPIRATORY</b>   | <b>SKIN</b> |
|    |  |  |             |
| <b>Environmental Exposure Controls:</b> Do not allow spills to enter sewers or waterways.   |   |  |             |
| <b>General Hygiene Considerations and Work Practices:</b> Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling. Eye wash facilities should be available in the work area.  |   |  |             |
| <b>Protective Measures During Repair and Maintenance of Contaminated Equipment:</b> Wear appropriate protective clothing and equipment.   |   |  |             |

## 9. PHYSICAL AND CHEMICAL PROPERTIES

|                    |                         |                          |  |
|--------------------|-------------------------|--------------------------|--|
| <b>Appearance:</b> | Paste in various colors | <b>Explosive limits:</b> | <b>LEL:</b> Not applicable<br><b>UEL:</b> Not applicable |
|--------------------|-------------------------|--------------------------|--|

|   |                |  |                             |
|---|----------------|--|-----------------------------|
| <b>Odor:</b>                            | Odorless       | <b>Vapor pressure (mmHg):</b>                  | Not applicable              |
| <b>Odor threshold:</b>                  | Not determined | <b>Vapor density:</b>                          | Not applicable              |
| <b>pH:</b>                              | Not applicable | <b>Relative density:</b>                       | 2.4-2.8 gm/cc @ 68°F (20°C) |
| <b>Melting/freezing point:</b>          | Not applicable | <b>Solubility:</b>                             | Insoluble in water (<0.1%)  |
| <b>Initial boiling point and range:</b> | Not applicable | <b>Partition coefficient: n-octanol/water:</b> | Not available               |
| <b>Flash point:</b>                     | Not applicable | <b>Auto-ignition temperature:</b>              | Not applicable              |
| <b>Evaporation rate:</b>                | Not determined | <b>Decomposition temperature:</b>              | Not determined              |
| <b>Flammability:</b>                    | Not flammable  | <b>Viscosity:</b>                              | Not determined              |
| <b>Explosive Properties:</b>            | Not explosive  | <b>Oxidizing Properties:</b>                   | None                        |
| <b>% Volatile by Volume:</b>            | Negligible     |  |                             |

## 10. STABILITY AND REACTIVITY

**Reactivity:** None known.

**Chemical Stability:** Stable. Does not degrade. Partially evaporates.

**Possibility of Hazardous Reactions:** None known.

**Conditions to Avoid:** None known.

**Incompatible materials:** Avoid strong oxidizing agents and reducing agents.

**Hazardous Decomposition Products:** When heated to decomposition emits oxides of carbon and butadiene.

## 11. TOXICOLOGICAL INFORMATION

### **Potential Health Effects:**

Eyes: Direct contact may cause irritation with redness, burning and tearing. Dust from grinding or polishing may cause mechanical irritation.

Skin: This product does not irritate skin.

Ingestion: No adverse effects are expected from swallowing small amounts.

Inhalation: Not expected to cause respiratory tract irritation.

|   |
|---|
| <b><u>Chronic Health Effects:</u></b> None known.   |
| <b><u>Carcinogenicity:</u></b> None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU Substances Directive.   |
| <b><u>Mutagenicity:</u></b> 1, 3 Butylene glycol: Rats were fed butane-1,3-diol in concentrations up to 24% of the diet and paired to produce F1A, F2A and F3A litters. Analysis of the femur bone marrow of at least two animal per sex and dose of these litters revealed no increase in chromosomal aberrations. Not mutagenic in vivo (rat dominant lethal and cytogenetic assays).   |
| <b><u>Medical Conditions Aggravated by Exposure:</u></b> Individuals with pre-existing skin, respiratory, liver and kidney disease may be at increased risk from exposure.  |
| <b><u>Acute Toxicity Data:</u></b><br>Sodium Potassium Aluminosilicate: No toxicity data available<br>1, 3 Butylene glycol: Oral rat LD50 – 18.6-30 g/kg<br>Di(propylene) Glycol: Oral rat LD50- >5000 mg/kg; Skin rabbit LD50- >5010 mg/kg   |
| <b><u>Reproductive Toxicity Data:</u></b> 1, 3 Butylene glycol: In a study of twenty five rats of both sexes were fed either control diet or diet supplemented with 1,3-butylene glycol at dose levels of 5, 10 or 24% of the diet (2500, 5000 or 12000 mg/kg by weight/day). 1,3-butylene glycol did not influence fertility in a five generation study with an embedded continuous breeding study in concentrations up to 10% in the diet (5000 mg/kg). In the highest concentration tested (24%, 12000 mg/kg) no offspring in the fifth litter of the F2 generation were produced. |
| <b><u>Specific Target Organ Toxicity (STOT):</u></b><br><b><u>Single Exposure:</u></b> No data available<br><br><b><u>Repeated Exposure:</u></b> 1, 3 Butylene glycol: No treatment related adverse effects were observed in a chronic feeding-study in rats which received up to 10% (5000 mg/kg/d) 1,3-butylene glycol in food.   |

## 12. ECOLOGICAL INFORMATION

|   |
|---|
| <b><u>Toxicity:</u></b><br>1, 3 Butylene glycol: 48hr EC50 Daphnia magna - >1000 mg/L; 72hr ErC50 Algae - >1070 mg/L<br>Di(propylene) Glycol: 48hr EC50 Daphnia magna - >109 mg/L |
| <b><u>Persistence and Degradability:</u></b> 1, 3 Butylene glycol: Readily biodegradable – 81% after 29 days.   |
| <b><u>Bio-accumulative Potential:</u></b> No data available   |
| <b><u>Mobility in Soil:</u></b> No data available   |
| <b><u>Other Adverse Effects:</u></b> Possible hazardous long term degradation products may arise.   |
| <b><u>Results of PBT/vPvB Assessment:</u></b> Not applicable.   |

## 13. DISPOSAL CONSIDERATIONS

|  |
|--|
| <b><u>Regulations:</u></b> Dispose in accordance with all national and local regulations.  |
| <b><u>Properties (Physical/Chemical) Affecting Disposal:</u></b> Empty containers retain product residues and can be hazardous. Follow all SDS precautions when handling empty containers. |
| <b><u>Waste Treatment Recommendations:</u></b> Dispose in accordance with national and local regulations.  |

## 14. TRANSPORT INFORMATION

|   |  |                           |            |           |
|---|--|---------------------------|------------|-----------|
| <b>UN Number:</b>                                   | ADR/RID: None  | IMDG: None                | IATA: None | DOT: None |
| <b>UN proper shipping name:</b>                     | ADR/RID: Not Regulated<br>IMDG: Not Regulated<br>IATA: Not Regulated<br>DOT: Not Regulated |                           |            |           |
| <b>Transport hazard class(es):</b>                  | ADR/RID: None  | IMDG: None                | IATA: None | DOT: None |
| <b>Packaging group:</b>                             | ADR/RID: None  | IMDG: None                | IATA: None | DOT: None |
| <b>Environmental hazards:</b>                       | ADR/RID: No  | IMDG Marine pollutant: No | IATA: No   | DOT: No   |
| <b>Special precautions for user:</b> Not applicable |  |                           |            |           |

## 15. REGULATORY INFORMATION

### U.S. Federal Regulations

**US OSHA Hazard Classification:** Not Hazardous

**Comprehensive Environmental Response and Liability Act of 1980 (CERCLA):** 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.

**Toxic Substances Control Act (TSCA):** All of the components of this product are listed on the TSCA inventory.

**Clean Water Act (CWA):** This material is not regulated under the Clean Water Act.

**Clean Air Act (CAA):** This material is not regulated under the Clean Air Act.

**Superfund Amendments and Reauthorization Act (SARA) Title III Information:**

**SARA Section 311/312 (40 CFR 370) Hazard Categories:**

|                          |    |                           |    |
|--------------------------|----|---------------------------|----|
| <b>Immediate Hazard:</b> | No | <b>Pressure Hazard:</b>   | No |
| <b>Delayed Hazard:</b>   | No | <b>Reactivity Hazard:</b> | No |
| <b>Fire Hazard:</b>      | No |                           |    |

**This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):**

| Components | C.A.S. # | WT % |
|------------|----------|------|
| None       |          |      |



### **State Regulations**

**California:** This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity:

| <b>Components</b> | <b>C.A.S. #</b> | <b>WT %</b> |
|-------------------|-----------------|-------------|
| None              |                 |             |

### **International Regulations**

**Canadian Workplace Hazardous Materials Information System (WHMIS):** Medical devices are not subject to WHMIS.

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

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

**European Inventory of Existing Chemicals (EINECS):** This product is a medical device and not subject to chemical notification requirements.

**EU REACH:** All components requiring registration have been pre-registered.

**Australian Inventory of Chemical Substances:** All of the components in this product are listed on the AICS for Australia.

**China Inventory of Existing Chemicals and Chemical Substances:** All of the components in this product are listed on the IECSC for China.

**Japanese Existing and New Chemical Substances:** All of the components in this product are listed on the Japanese ENCS lists.

**Korean Existing Chemicals List:** All of the components in this product are listed on the KECL for Korea.

**Philippine Inventory of Chemicals and Chemical Substances:** All of the components in this product are listed on the PICCS.

## **16. OTHER INFORMATION**

### **HMIS Hazard Rating:**

Health – 1      Flammability – 1      Physical Hazard – 0

Full text of Classification abbreviations used in Section 2 and 3:

None

Supersedes: 06 June 2013

Revision Summary: Updated SDS to current format.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.

# DENTSPLY International

## DENTSPLY PROSTHETICS

### Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: 06 June 2013  
Document Number: 452  
Date Revised: 11 September 2013  
New

#### 1. PRODUCT IDENTIFICATION

**Trade Name (as labeled):** CELTRA™ Universal Overglaze, Universal Stain

**Product Identifier (Part/Item Number):** Overglaze: 601322; Stain: 601500-601505, 601511, 601512, 601520-601526

**U.N. Number:** Not Regulated

**U.N. Dangerous Goods Classification:** Not Regulated

**Recommended Use:** Used for staining and glazing CELTRA DUO and other lithium silicate based restorations and Cercon zirconia.

**Restrictions on Use:** For Professional Use Only

**Manufacturer/Supplier Name:** Dentsply Prosthetics

**Manufacturer/Supplier Address:** 570 West College Ave.  
York, PA 17405-0872

**Manufacturer/Supplier Telephone Number:** 717-845-7511 (Product Information)

**Emergency Contact Telephone Number:** 800-424-9300 Chemtrec

**Email address:** Prosthetics\_MSDS@Dentsply.com

#### 2. HAZARD(s) IDENTIFICATION

**EU Classification (1999/45/EC):** Not a dangerous preparation

**Refer to Section 16 for the full text of the EU Classifications and R Phrases.**

**Labeling in accordance with 1999/45/EC**

None Required

**US Hazard Classification:** Not Hazardous

#### 3. COMPOSITION AND INFORMATION ON INGREDIENTS

| Hazardous Components             | C.A.S. #    | EINECS #    | Substance Classification | WT %  |
|----------------------------------|-------------|-------------|--------------------------|-------|
| Sodium Potassium Aluminosilicate | Proprietary | Proprietary | Not Applicable           | 60-70 |

|                      |            |           |                |      |
|----------------------|------------|-----------|----------------|------|
| 1, 3 Butylene Glycol | 107-88-0   | 203-529-7 | Not Applicable | 0-18 |
| Di(propylene) Glycol | 25265-71-8 | 246-770-3 | Not Applicable | 0-12 |





The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS and H phrases and EU Classifications and R Phrases.

#### 4. FIRST-AID MEASURES





| Routes of Exposure   | First Aid Instructions   |
|--|--|
| Eye  | Flush victim's eyes with water, while holding the eyelids apart. Check victim for contact lenses and remove if possible while flushing. Get medical attention if irritation occurs and persists. |
| Skin   | Wash skin with plenty of water. Get medical attention if irritation develops or persists.  |
| Inhalation   | Remove victim to fresh air. Get medical attention if irritation develops.  |
| Ingestion  | If small quantities are swallowed, rinse out mouth with water. Do not induce vomiting. If irritation or discomfort occurs, get medical attention.  |
| Most important symptoms of exposure  | May cause eye irritation.  |
| <b>Note to Physicians (Treatment, Testing, and Monitoring):</b> Treat symptomatically. Immediate medical attention should not be required. |  |

#### 5. FIRE-FIGHTING MEASURES

|   |  |  |   |
|---|--|--|---|
| <b>Suitable Extinguishing Media:</b>  | Use dry chemical, carbon dioxide, alcohol or polymer foam.   |  |   |
| <b>Fire Fighting Procedures:</b>  | Use water to cool fire-exposed containers.   |  |   |
| <b>Specific Hazards Arising from the Chemical:</b>                                  | Decomposition may release oxides of carbon and butadiene.  |  |   |
| <b>Precautions for Fire Fighters:</b>   | Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. |  |   |
| <b>Recommended Protective Equipment for Fire Fighters:</b>                          |  |  |   |
| <b>EYES/FACE</b>  | <b>HANDS</b>   | <b>RESPIRATORY</b>   | <b>THERMAL</b>  |
|  |                                   |  |  |

#### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, PPE and Emergency Procedures:** Evacuate spill area and keep unprotected personnel away. Ventilate area. Wear appropriate protective clothing as described in Section 8. Avoid contact with skin, eyes or clothing.

|  |   |  |   |
|--|---|--|---|
| Avoid breathing vapors.  |   |  |   |
| <b>Environmental Precautions:</b> Prevent entry into sewers and waterways. Report releases as required by local and national authorities.        |   |  |   |
| <b>Methods and Materials for Containment and Clean-up:</b> Promptly wipe up or scoop up spills and place in appropriate containers for disposal. |   |  |   |
| <b>Recommended Personal Protective Equipment for Containment and Clean-up:</b>   |   |  |   |
| <b>EYES/FACE</b>   | <b>HANDS</b>  | <b>RESPIRATORY</b>   | <b>SKIN</b>   |
|   |  |  |  |

## 7. HANDLING AND STORAGE

**Precautions for Safe Handling:** Avoid contact with the eyes, skin and clothing. Avoid breathing vapors. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use.



Do not reuse containers. Empty containers retain product residues and can be hazardous. Follow all SDS precautions when handling empty containers.

**Conditions for Safe Storage:** Store in a cool, dry, well-ventilated area away from incompatible materials. Keep container tightly closed.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Occupational Exposure Limits:

|                                  |               |                  |
|----------------------------------|---------------|------------------|
| Sodium Potassium Aluminosilicate | United States | None Established |
|----------------------------------|---------------|------------------|

|   |   |  |             |
|---|---|--|-------------|
|   | Germany   | None Established   |             |
|   | United Kingdom  | None Established   |             |
|   | European Union  | None Established   |             |
| 1, 3 Butylene glycol  | United States   | None Established   |             |
|   | Germany   | None Established   |             |
|   | United Kingdom  | None Established   |             |
|   | European Union  | None Established   |             |
| Di(propylene) Glycol  | United States   | None Established   |             |
|   | Germany   | 100 mg/m <sup>3</sup> (Inhalable, Sum of vapor and aerosol) TWA, 200 mg/m <sup>3</sup> STEL DFG MAK (Skin) |             |
|   | United Kingdom  | None Established   |             |
|   | European Union  | None Established   |             |
| <b>Biological Exposure Limits:</b> None Established.  |   |  |             |
| <b>Appropriate Engineering Controls:</b> Use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits.  |   |  |             |
| <b>Individual Protection Measures (PPE)</b><br><b>Specific Eye/face Protection:</b> Chemical safety glasses are recommended to avoid contact.<br><b>Specific Skin Protection:</b> No special protection is required.<br><b>Specific Respiratory Protection:</b> None should be needed for normal use. If the exposure limits are exceeded an approved organic vapor respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice.<br><b>Specific Thermal Hazards:</b> None required. |   |  |             |
| <b>Recommended Personal Protective Equipment</b>  |   |  |             |
| <b>EYES/FACE</b>  | <b>HANDS</b>  | <b>RESPIRATORY</b>   | <b>SKIN</b> |
|    |  |  |             |
| <b>Environmental Exposure Controls:</b> Do not allow spills to enter sewers or waterways.   |   |  |             |
| <b>General Hygiene Considerations and Work Practices:</b> Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling. Eye wash facilities should be available in the work area.  |   |  |             |
| <b>Protective Measures During Repair and Maintenance of Contaminated Equipment:</b> Wear appropriate protective clothing and equipment.   |   |  |             |

## 9. PHYSICAL AND CHEMICAL PROPERTIES

|                    |                         |                          |  |
|--------------------|-------------------------|--------------------------|--|
| <b>Appearance:</b> | Paste in various colors | <b>Explosive limits:</b> | <b>LEL:</b> Not applicable<br><b>UEL:</b> Not applicable |
|--------------------|-------------------------|--------------------------|--|

|   |                |  |                             |
|---|----------------|--|-----------------------------|
| <b>Odor:</b>                            | Odorless       | <b>Vapor pressure (mmHg):</b>                  | Not applicable              |
| <b>Odor threshold:</b>                  | Not determined | <b>Vapor density:</b>                          | Not applicable              |
| <b>pH:</b>                              | Not applicable | <b>Relative density:</b>                       | 2.4-2.8 gm/cc @ 68°F (20°C) |
| <b>Melting/freezing point:</b>          | Not applicable | <b>Solubility:</b>                             | Insoluble in water (<0.1%)  |
| <b>Initial boiling point and range:</b> | Not applicable | <b>Partition coefficient: n-octanol/water:</b> | Not available               |
| <b>Flash point:</b>                     | Not applicable | <b>Auto-ignition temperature:</b>              | Not applicable              |
| <b>Evaporation rate:</b>                | Not determined | <b>Decomposition temperature:</b>              | Not determined              |
| <b>Flammability:</b>                    | Not flammable  | <b>Viscosity:</b>                              | Not determined              |
| <b>Explosive Properties:</b>            | Not explosive  | <b>Oxidizing Properties:</b>                   | None                        |
| <b>% Volatile by Volume:</b>            | Negligible     |  |                             |

## 10. STABILITY AND REACTIVITY

**Reactivity:** None known.

**Chemical Stability:** Stable. Does not degrade. Partially evaporates.

**Possibility of Hazardous Reactions:** None known.

**Conditions to Avoid:** None known.

**Incompatible materials:** Avoid strong oxidizing agents and reducing agents.

**Hazardous Decomposition Products:** When heated to decomposition emits oxides of carbon and butadiene.

## 11. TOXICOLOGICAL INFORMATION

### **Potential Health Effects:**

**Eyes:** Direct contact may cause irritation with redness, burning and tearing. Dust from grinding or polishing may cause mechanical irritation.

**Skin:** This product does not irritate skin.

**Ingestion:** No adverse effects are expected from swallowing small amounts.

**Inhalation:** Not expected to cause respiratory tract irritation.

|   |
|---|
| <b><u>Chronic Health Effects:</u></b> None known.   |
| <b><u>Carcinogenicity:</u></b> None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU Substances Directive.   |
| <b><u>Mutagenicity:</u></b> 1, 3 Butylene glycol: Rats were fed butane-1,3-diol in concentrations up to 24% of the diet and paired to produce F1A, F2A and F3A litters. Analysis of the femur bone marrow of at least two animal per sex and dose of these litters revealed no increase in chromosomal aberrations. Not mutagenic in vivo (rat dominant lethal and cytogenetic assays).   |
| <b><u>Medical Conditions Aggravated by Exposure:</u></b> Individuals with pre-existing skin, respiratory, liver and kidney disease may be at increased risk from exposure.  |
| <b><u>Acute Toxicity Data:</u></b><br>Sodium Potassium Aluminosilicate: No toxicity data available<br>1, 3 Butylene glycol: Oral rat LD50 – 18.6-30 g/kg<br>Di(propylene) Glycol: Oral rat LD50- >5000 mg/kg; Skin rabbit LD50- >5010 mg/kg   |
| <b><u>Reproductive Toxicity Data:</u></b> 1, 3 Butylene glycol: In a study of twenty five rats of both sexes were fed either control diet or diet supplemented with 1,3-butylene glycol at dose levels of 5, 10 or 24% of the diet (2500, 5000 or 12000 mg/kg by weight/day). 1,3-butylene glycol did not influence fertility in a five generation study with an embedded continuous breeding study in concentrations up to 10% in the diet (5000 mg/kg). In the highest concentration tested (24%, 12000 mg/kg) no offspring in the fifth litter of the F2 generation were produced. |
| <b><u>Specific Target Organ Toxicity (STOT):</u></b><br><b><u>Single Exposure:</u></b> No data available<br><br><b><u>Repeated Exposure:</u></b> 1, 3 Butylene glycol: No treatment related adverse effects were observed in a chronic feeding-study in rats which received up to 10% (5000 mg/kg/d) 1,3-butylene glycol in food.   |

## 12. ECOLOGICAL INFORMATION

|   |
|---|
| <b><u>Toxicity:</u></b><br>1, 3 Butylene glycol: 48hr EC50 Daphnia magna - >1000 mg/L; 72hr ErC50 Algae - >1070 mg/L<br>Di(propylene) Glycol: 48hr EC50 Daphnia magna - >109 mg/L |
| <b><u>Persistence and Degradability:</u></b> 1, 3 Butylene glycol: Readily biodegradable – 81% after 29 days.   |
| <b><u>Bio-accumulative Potential:</u></b> No data available   |
| <b><u>Mobility in Soil:</u></b> No data available   |
| <b><u>Other Adverse Effects:</u></b> Possible hazardous long term degradation products may arise.   |
| <b><u>Results of PBT/vPvB Assessment:</u></b> Not applicable.   |

## 13. DISPOSAL CONSIDERATIONS

|  |
|--|
| <b><u>Regulations:</u></b> Dispose in accordance with all national and local regulations.  |
| <b><u>Properties (Physical/Chemical) Affecting Disposal:</u></b> Empty containers retain product residues and can be hazardous. Follow all SDS precautions when handling empty containers. |
| <b><u>Waste Treatment Recommendations:</u></b> Dispose in accordance with national and local regulations.  |

## 14. TRANSPORT INFORMATION

|   |  |                           |            |           |
|---|--|---------------------------|------------|-----------|
| <b>UN Number:</b>                                   | ADR/RID: None  | IMDG: None                | IATA: None | DOT: None |
| <b>UN proper shipping name:</b>                     | ADR/RID: Not Regulated<br>IMDG: Not Regulated<br>IATA: Not Regulated<br>DOT: Not Regulated |                           |            |           |
| <b>Transport hazard class(es):</b>                  | ADR/RID: None  | IMDG: None                | IATA: None | DOT: None |
| <b>Packaging group:</b>                             | ADR/RID: None  | IMDG: None                | IATA: None | DOT: None |
| <b>Environmental hazards:</b>                       | ADR/RID: No  | IMDG Marine pollutant: No | IATA: No   | DOT: No   |
| <b>Special precautions for user:</b> Not applicable |  |                           |            |           |

## 15. REGULATORY INFORMATION

### U.S. Federal Regulations

**US OSHA Hazard Classification:** Not Hazardous

**Comprehensive Environmental Response and Liability Act of 1980 (CERCLA):** 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.

**Toxic Substances Control Act (TSCA):** All of the components of this product are listed on the TSCA inventory.

**Clean Water Act (CWA):** This material is not regulated under the Clean Water Act.

**Clean Air Act (CAA):** This material is not regulated under the Clean Air Act.

**Superfund Amendments and Reauthorization Act (SARA) Title III Information:**

**SARA Section 311/312 (40 CFR 370) Hazard Categories:**

|                          |    |                           |    |
|--------------------------|----|---------------------------|----|
| <b>Immediate Hazard:</b> | No | <b>Pressure Hazard:</b>   | No |
| <b>Delayed Hazard:</b>   | No | <b>Reactivity Hazard:</b> | No |
| <b>Fire Hazard:</b>      | No |                           |    |

**This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):**

| Components | C.A.S. # | WT % |
|------------|----------|------|
| None       |          |      |



### **State Regulations**

**California:** This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity:

| <b>Components</b> | <b>C.A.S. #</b> | <b>WT %</b> |
|-------------------|-----------------|-------------|
| None              |                 |             |

### **International Regulations**

**Canadian Workplace Hazardous Materials Information System (WHMIS):** Medical devices are not subject to WHMIS.

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

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

**European Inventory of Existing Chemicals (EINECS):** This product is a medical device and not subject to chemical notification requirements.

**EU REACH:** All components requiring registration have been pre-registered.

**Australian Inventory of Chemical Substances:** All of the components in this product are listed on the AICS for Australia.

**China Inventory of Existing Chemicals and Chemical Substances:** All of the components in this product are listed on the IECSC for China.

**Japanese Existing and New Chemical Substances:** All of the components in this product are listed on the Japanese ENCS lists.

**Korean Existing Chemicals List:** All of the components in this product are listed on the KECL for Korea.

**Philippine Inventory of Chemicals and Chemical Substances:** All of the components in this product are listed on the PICCS.

## **16. OTHER INFORMATION**

### **HMIS Hazard Rating:**

Health – 1      Flammability –1      Physical Hazard– 0

Full text of Classification abbreviations used in Section 2 and 3:

None

Supersedes: 06 June 2013

Revision Summary: Updated SDS to current format.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.