

SAFETY DATA SHEETS

This SDS packet was issued with item:

071830355

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).

071829928 071829936 071829944 071829951 071829969 071830306 071830314 071830322 071830330 071830348

071830363 078319106 078319109 078319112 078319115 078319118 078319121

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

569898

1. Identification

| | |
|--|---|
| Product Name SmartCem[®] 2 | SDS Code Number 569898 |
| Substance Identity SmartCem[®] 2 Self-Adhesive Cement | Date of Last Revision 09/14/11 |
| Manufacturer: DENTSPLY Caulk | Address 38 West Clarke Avenue Milford DE 19963-1805 http://www.caulk.com http://www.dentsply.com |
| Grades or Minor Variant Identities Not Applicable | Information Telephone Number (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time) |
| Product Use (for Canada) Dual Curing Dental Luting Cement | Emergency Telephone Number (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time) |

2. Hazard(s) Identification



WARNING

MAY CAUSE AN ALLERGIC SKIN

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 | % |
|--|------------------------|-----------------------|-----------|
| Silanated Barium Boron Fluoro Alumino Silicate Glass | 65997-18-4, 2530-85-0 | 10 mg/m ³ | < than 75 |
| Polymerizable dimethacrylate resin | 105883-40-7 | Not Established | < 10 |
| Polymerizable trimethacrylate resin | 3290-92-4 | Not Established | < 10 |
| Polymerizable dimethacrylate resin | 41637-38-1 | Not Established | < 10 |
| Polymerizable dimethacrylate resin | 109-16-0 | Not Established | < 10 |
| Polymerizable dimethacrylate resin | 868-77-9 | Not Established | < 10 |
| Polymerizable dimethacrylate resin | 1709-71-3 | Not Established | < 5 |
| Strontium Fluoride | 7783-48-4 | 2.5 mg/m ³ | < 10 |
| Hydrophobic Amorphous Silica | 67762-90-7, 68611-44-9 | 3 mg/m ³ | < than 5 |

Other Information: Colorants are inorganic iron oxides.

3. Composition/Information on Ingredients – Catalyst Paste

| Hazardous Components | C.A.S. Number | Exposure Limits | % |
|--|------------------------|----------------------|-----------|
| Barium Boron Fluoro Alumino Silicate Glass | 65997-18-4, 2530-85-0 | 10 mg/m ³ | < than 75 |
| Urethane Dimethacrylate Resin | 105883-40-7 | Not Established | < than 10 |
| Urethane Modified Bis-GMA Dimethacrylate Resin | 41637-38-1 | Not Established | < than 10 |
| Polymerizable Dimethacrylate Resins | 3290-92-4/109-16-0 | Not Established | < than 10 |
| Dipentaerythritol Pentaacrylate Phosphate | 87699-25-0 | Not Established | < than 10 |
| Hydrophobic Amorphous Silica | 67762-90-7, 68611-44-9 | 3 mg/m ³ | < than 5 |

4. First Aid Measures

| Routes of Exposure | First Aid Instructions | Immediate Medical Attention | Delayed Effects |
|--------------------|---|-----------------------------|-----------------|
| Eye | Rinse opened eye for several minutes under running water. | Not Applicable | Not Applicable |

| | | | |
|------------|--|----------------|----------------|
| | If symptoms persist consult physician | | |
| Skin | Immediately wash with soap and water and rinse thoroughly | Not Applicable | Not Applicable |
| Inhalation | Not Applicable | Not Applicable | Not Applicable |
| Ingestion | Not Applicable | Not Applicable | Not Applicable |
| Mucosa | Rinse tissue for several minutes under running water. If symptoms persist consult physician | Not Applicable | Not Applicable |

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

5. Fire Fighting Measures

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

6. Accidental Release Measures

| | | |
|--|--------------------------------------|--|
| Containment Techniques: Material is a paste and as such will not flow. | | |
| Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container. Avoid gross skin contact to minimize the possibility of contact dermatitis to susceptible persons. Ensure adequate ventilation. | | |
| Evacuation Procedures: Not Applicable | Special Instructions: Not Applicable | Reporting Requirements: Not Applicable |

7. Handling and Storage

| |
|---|
| Handling Practices and Warnings: Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals. |
| Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Protect from exposure to direct light. Store away from food and beverages. |

8. Exposure Control / Personal Protection



| Occupational Exposure Limits: Not Applicable | | |
|--|--|---|
| Engineering Controls: Not Applicable | | |
| Individual Protection Measures | Personal Protective Equipment for Normal Use | Personal Protective Equipment for 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 |

9. Physical and Chemical Characteristics

| | |
|--|---|
| Appearance: Creamy viscous paste. Multiple shades. | Odor: Characteristic sweet acrylic ester odor. |
| Normal Physical State: High Viscosity Liquid (Paste) | Melting Point: Not Applicable |
| Specific Gravity: 1.8-1.9 g/cm ³ | Solubility in Water: Not soluble |
| Vapor Pressure (mm Hg): Not Applicable | pH: Not Applicable |
| Flashpoint Method: Not Applicable | Evaporation Rate (Butyl Acetate =1): Not Applicable |
| Flammable (Explosive) Limits in Air LEL: Not Applicable UEL: Not Applicable | 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: <input type="checkbox"/> May Occur <input checked="" type="checkbox"/> May Not Occur | Conditions to Avoid: None known |
| Stability? <input checked="" type="checkbox"/> Stable <input type="checkbox"/> Unstable | Conditions to Avoid: None known |

11. Toxicological Information

| | | | | | |
|---|--|----------------------|-----------------|------------------------------------|-----------------|
| Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data: Product is an irritant to the skin and mucous membranes. The unpolymerized product may be an irritant to the skin in susceptible persons. On the eye the product has an irritating effect. Sensitization: Repeated or prolonged contact with the unpolymerized material may cause sensitization for persons allergic to acrylates and methacrylates. This product shows the following dangers according to internally approved calculation methods for composite materials: Irritant. | | | | | |
| Emergency Overview Material is irritating to eyes, respiratory system and skin. | | | | | |
| Routes of | | Single, Repeated, or | Severity (Mild, | Acute and Chronic Health Effect(s) | Target Organ(s) |

| Exposure | Signs and Symptoms | Lifetime Exposure | Moderate, Severe) | | |
|---|---|-------------------|-------------------|--|----------------|
| 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. Severe allergic response may result in breathing difficulties. | Not Applicable |
| Inhalation | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable |
| Ingestion | Material is not harmful if swallowed using clinically relevant quantities | Not Applicable | Mild | Not Applicable | Not Applicable |
| Mucosa | Material can cause irritation. | Single | Mild | Inflammation of the mucosa | Not Applicable |
| Medical Conditions Aggravated by Exposure Open sores and wounds of the skin. Individuals with known sensitivity to methacrylates, acrylates, or urethane dimethacrylate resin used in Dental restorative products. | | | | | |
| Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory. | | | | | |
| Potential Environmental Effects Do not allow to enter sewers/ surface or ground water. | | | | | |
| NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 1, Reactivity = 0 | | | | | |

12. Ecological Information

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

15. Regulatory Information

| |
|---|
| This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations. |
| U.S. Federal Regulations: <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 |
| <u>Section 302 Extremely Hazardous Substances (TPQ)</u> : None |
| <u>EPA Toxic Substances Control Act (TSCA) Status</u> : All of the components of this product are listed on the TSCA inventory. |
| <u>U.S. State Regulations California Proposition 65</u> : This product does not contain any chemicals, which are on the California Proposition 65 list. |
| <u>International Regulations: Canadian Environmental Protection Act</u> : This product is a medical device and not subject to chemical notification requirements. |
| <u>European Community Labeling</u> : Not a dangerous preparation. |
| <u>European Inventory of New and Existing Chemicals Substances (EINECS)</u> : 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.



1. Identification

| | |
|--|--|
| Product Name SmartCem[®] 2 | SDS Code Number 569898 |
| Substance Identity SmartCem[®] 2 Self-Adhesive Cement | Date of Last Revision 03/16/17 |
| Manufacturer: DENTSPLY Caulk | Address 38 West Clarke Avenue Milford DE 19963-1805 http://www.dentsply.com |
| Grades or Minor Variant Identities Not Applicable | Company Telephone Number (Product Inquiries) (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time) |
| Product Use (for Canada) Dual Curing Dental Luting Cement | Emergency Telephone Number CHEMTREC: 1-800-424-9300 (24 hours) (Outside U.S. +1-703-527-3887) CCN6510 |

2. Hazard(s) Identification



WARNING

MAY CAUSE AN ALLERGIC SKIN

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 | % |
|--|------------------------|-----------------------|-----------|
| Silanated Barium Boron Fluoro Alumino Silicate Glass | 65997-18-4, 2530-85-0 | 10 mg/m ³ | < than 75 |
| Polymerizable dimethacrylate resin | 105883-40-7 | Not Established | < 10 |
| Polymerizable trimethacrylate resin | 3290-92-4 | Not Established | < 10 |
| Polymerizable dimethacrylate resin | 41637-38-1 | Not Established | < 10 |
| Polymerizable dimethacrylate resin | 109-16-0 | Not Established | < 10 |
| Polymerizable dimethacrylate resin | 868-77-9 | Not Established | < 10 |
| Polymerizable dimethacrylate resin | 1709-71-3 | Not Established | < 5 |
| Strontium Fluoride | 7783-48-4 | 2.5 mg/m ³ | < 10 |
| Hydrophobic Amorphous Silica | 67762-90-7, 68611-44-9 | 3 mg/m ³ | < than 5 |

Other Information: Colorants are inorganic iron oxides.

3. Composition/Information on Ingredients – Catalyst Paste

| Hazardous Components | C.A.S. Number | Exposure Limits | % |
|--|------------------------|----------------------|-----------|
| Barium Boron Fluoro Alumino Silicate Glass | 65997-18-4, 2530-85-0 | 10 mg/m ³ | < than 75 |
| Urethane Dimethacrylate Resin | 105883-40-7 | Not Established | < than 10 |
| Urethane Modified Bis-GMA Dimethacrylate Resin | 41637-38-1 | Not Established | < than 10 |
| Polymerizable Dimethacrylate Resins | 3290-92-4/109-16-0 | Not Established | < than 10 |
| Dipentaerythritol Pentaacrylate Phosphate | 87699-25-0 | Not Established | < than 10 |
| Hydrophobic Amorphous Silica | 67762-90-7, 68611-44-9 | 3 mg/m ³ | < than 5 |

4. First Aid Measures

| Routes of Exposure | First Aid Instructions | Immediate Medical Attention | Delayed Effects |
|--------------------|---|-----------------------------|-----------------|
| Eye | Rinse opened eye for several minutes under running water. | Not Applicable | Not Applicable |

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

5. Fire Fighting Measures

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

6. Accidental Release Measures

| | | |
|--|--------------------------------------|--|
| Containment Techniques: Material is a paste and as such will not flow. | | |
| Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container. Avoid gross skin contact to minimize the possibility of contact dermatitis to susceptible persons. Ensure adequate ventilation. | | |
| Evacuation Procedures: Not Applicable | Special Instructions: Not Applicable | Reporting Requirements: Not Applicable |

7. Handling and Storage

| |
|---|
| Handling Practices and Warnings: Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals. |
| Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Protect from exposure to direct light. Store away from food and beverages. |

8. Exposure Control / Personal Protection



| | | |
|--|--|---|
| Occupational Exposure Limits: Not Applicable | | |
| Engineering Controls: Not Applicable | | |
| Individual Protection Measures | Personal Protective Equipment for Normal Use | Personal Protective Equipment for 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 |

9. Physical and Chemical Characteristics

| | |
|--|---|
| Appearance: Creamy viscous paste. Multiple shades. | Odor: Characteristic sweet acrylic ester odor. |
| Normal Physical State: High Viscosity Liquid (Paste) | Melting Point: Not Applicable |
| Specific Gravity: 1.8-1.9 g/cm ³ | Solubility in Water: Not soluble |
| Vapor Pressure (mm Hg): Not Applicable | pH: Not Applicable |
| Flashpoint Method: Not Applicable | Evaporation Rate (Butyl Acetate =1): Not Applicable |
| Flammable (Explosive) Limits in Air LEL: Not Applicable UEL: Not Applicable | 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: <input type="checkbox"/> May Occur <input checked="" type="checkbox"/> May Not Occur | Conditions to Avoid: None known |
| Stability? <input checked="" type="checkbox"/> Stable <input type="checkbox"/> Unstable | Conditions to Avoid: None known |

11. Toxicological Information

| |
|--|
| <p>Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data: Product is an irritant to the skin and mucous membranes. The unpolymerized product may be an irritant to the skin in susceptible persons. On the eye the product has an irritating effect. Sensitization: Repeated or prolonged contact with the unpolymerized material may cause sensitization for persons allergic to acrylates and methacrylates. This product shows the following dangers according to internally approved calculation methods for composite materials: Irritant.</p> <p>Emergency Overview Material is irritating to eyes, respiratory system and skin.</p> |
|--|

| Routes of Exposure | Signs and Symptoms | Single, Repeated, or Lifetime Exposure | Severity (Mild, Moderate, Severe) | Acute and Chronic Health Effect(s) | 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. Severe allergic response may result in breathing difficulties. | Not Applicable |
| Inhalation | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable |
| Ingestion | Material is not harmful if swallowed using clinically relevant quantities | Not Applicable | Mild | Not Applicable | Not Applicable |
| Mucosa | Material can cause irritation. | Single | Mild | Inflammation of the mucosa | Not Applicable |
| Medical Conditions Aggravated by Exposure Open sores and wounds of the skin. Individuals with known sensitivity to methacrylates, acrylates, or urethane dimethacrylate resin used in Dental restorative products. | | | | | |
| Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory. | | | | | |
| Potential Environmental Effects Do not allow to enter sewers/ surface or ground water. | | | | | |
| NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 1, Reactivity = 0 | | | | | |

12. Ecological Information

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

15. Regulatory Information

| |
|---|
| This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations. |
| U.S. Federal Regulations: <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. |
| 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.