

SAFETY DATA SHEETS

This SDS packet was issued with item:

071810308

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

071719376 071810290 078306250

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

531898

1. Identification

| | |
|--|--|
| Product Name PRISMA[®] GLOSS[™] & PRISMA[®] GLOSS[™] ExtraFine | SDS Code Number 531898 |
| Substance Identity PRISMA[®] GLOSS[™] & PRISMA[®] GLOSS[™] ExtraFine | Date of Last Revision 04/15/11 |
| 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) Not Applicable | Emergency Telephone Number (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time) |

2. Hazard(s) Identification



Warning

Causes serious eye irritation

Wash hands thoroughly after handling

Wear protective gloves, face protection.

If in eyes: Rinse cautiously with water for several minutes.

Remove contact lens, if present and easy to do. Continue rinsing.

Do not rub affected areas.

If eye irritation persists: Get medical advice attention.

3. Composition/Information on Ingredients

| Hazardous Components | C.A.S. Number | Exposure Limits | % |
|------------------------------------|---------------|----------------------|------|
| Aluminum Oxide | 1344-28-1 | 10 mg/M ³ | < 65 |
| Glycerine | 56-81-5 | 10 mg/M ³ | < 50 |
| Hydrophobic Amorphous Fumed Silica | 68611-44-9 | 3 mg/M ³ | < 5 |

3. Hazard Identification

| Emergency Overview: Material may be irritating to eyes. No significant hazards for emergency responses are known. | | | | | |
|---|--|--|-----------------------------------|--|-----------------|
| 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 may cause slight transient (temporary) irritation. | Single & Repeated | Moderate | Irritation and possible corneal damage due to the fillers used in the product. | Not Applicable |
| Skin | Material may be an irritant after repeated and prolonged exposure. | Repeated | Mild | Irritation or possible allergic response. | Not Applicable |
| Inhalation | Vapors are minimal due to physical properties. | Not Applicable | Not Applicable | Not Applicable | Not Applicable |
| Ingestion | Material is probably not harmful if swallowed | Not Applicable | Mild | Not Applicable | Not Applicable |
| Other | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable |
| Medical Conditions Aggravated by Exposure Open sores and wounds of the skin. | | | | | |
| Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory. | | | | | |
| Potential Environmental Effects Do not allow to enter sewers/ surface or ground water. | | | | | |
| NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 0, Reactivity = 0 | | | | | |

4. First Aid Measures

| Routes of 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 | Supply fresh air, consult physician if symptoms persist. | Not Applicable | Not Applicable |
| Ingestion | If symptoms persist consult physician. Do not induce vomiting unless instructed to do so by medical personnel. | Not Applicable | Not Applicable |
| Other | Not Applicable | Not Applicable | Not Applicable |
| Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically. | | | |

5. Fire and Explosion Data

| | | | |
|---|---|--|-----------------------|
| Flashpoint Method: 390°F (199°C) for Glycerine. Pensky-Martin Closed Cup | Flammable (Explosive) Limits in Air LEL: Not Applicable UEL: Not Applicable | Autoignition Temperature: 698°F (370°C) | Other: Not Applicable |
| Flame Propagation or Burning Rate (for Solids) Not Applicable | Properties Contributing to Fire Intensity: Not Applicable | Flammability Classification: Not Applicable | |
| Extinguishing Media: CO ₂ , Water fog or fine spray, foam, carbon dioxide or alcohol resistant foams (ATC Type). | | 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: During a fire, smoke may contain glycerine in addition to unidentified toxic and/or irritating compounds. Hazardous combustion products may include but not limited to aldehydes, carbon monoxide and carbon dioxide. | | | |

6. Accidental Release Measures

| | | |
|--|--------------------------------------|--|
| Containment Techniques: Material is a high viscosity paste, but will flow somewhat. | | |
| Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container. | | |
| Evacuation Procedures: Not Applicable | Special Instructions: Not Applicable | Reporting Requirements: Not Applicable |

7. Handling and Storage

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| Handling Practices and Warnings: Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals. |
| Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Store away from food and beverages. Glycerine freezes at 64°F (18°C). Product should be kept above 64°F (18°C) but less than 130°F (54°C). |

8. Exposure Control / Personal Protection



| 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 |
| Occupational Exposure Limits: Not Applicable | | Engineering Controls: Not Applicable |

9. Physical and Chemical Characteristics

| | | |
|--|--|--|
| Appearance: Creamy viscous white paste. | | Odor: Mild odor. |
| Normal Physical State: High Viscosity Liquid (Paste) | | Melting Point: Not Applicable |
| Specific Gravity: 1.7 g/cm ³ | Solubility in Water: Partially soluble. | pH: Not Applicable |
| Vapor Pressure (mm Hg): Not Applicable | Vapor Density (AIR=1): Not Applicable | Evaporation Rate (Butyl Acetate =1): N A |
| Flashpoint Method: Not Applicable | Flammable (Explosive) Limits in Air LEL: Not Applicable UEL: Not Applicable | Autoignition Temperature: Not Applicable |
| Other: Not Applicable | | |

10. Stability and Reactivity Data

| | |
|---|---------------------------------|
| Incompatibility (Materials to Avoid): Strong Oxidizing materials such as Sodium Hypochlorite or Hypochlorous Acid | |
| Hazardous Products Produced During Decomposition: Acrolein. | |
| Hazardous Polymerization: <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: For ingestion, the LD ₅₀ for glycerine in Rats is 17,000 – 27,000 mg/Kg. | | | | | |
|---|---|--|-----------------------------------|--|-----------------|
| Emergency Overview: Material may be mildly irritating to eyes. | | | | | |
| 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 may cause slight transient (temporary) irritation. | Single & Repeated | Moderate | Irritation and possible corneal damage due to the fillers used in the product. | Not Applicable |

| | | | | | |
|---|--|----------------|----------------|---|----------------|
| Skin | Material may be an irritant after repeated and prolonged exposure. | Repeated | Mild | Irritation or possible allergic response. | Not Applicable |
| Inhalation | Vapors are minimal due to physical properties. | Not Applicable | Not Applicable | Not Applicable | Not Applicable |
| Ingestion | Material is probably not harmful if swallowed | Not Applicable | Mild | Not Applicable | Not Applicable |
| Other | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable |
| Medical Conditions Aggravated by Exposure Open sores and wounds of the skin. | | | | | |
| Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory. | | | | | |
| Potential Environmental Effects: 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 class I (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. 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: CERCLA 103 Reportable Quantity: This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations

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

Section 302 Extremely Hazardous Substances (TPQ): None

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

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

International Regulations: Canadian Environmental Protection Act:

This product is a medical device and not subject to chemical notification requirements.

European Community Labeling: Not a dangerous preparation.

European Inventory of New and Existing Chemicals Substances (EINECS):

This product is a medical device and not subject to chemical notification requirements.

Other: Not Applicable

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

531898

1. Identification

| | |
|--|--|
| Product Name PRISMA® GLOSS™ & PRISMA® GLOSS™ ExtraFine | SDS Code Number 531898 |
| Substance Identity PRISMA® GLOSS™ & PRISMA® GLOSS™ ExtraFine | Date of Last Revision 02/02/17 |
| Manufacturer: DENTSPLY Milford | Address 38 West Clarke Avenue Milford DE 19963-1805 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) Not Applicable | Emergency Telephone Number (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time) |

2. Hazard(s) Identification



Warning

Causes serious eye irritation

Wash hands thoroughly after handling

Wear protective gloves, face protection.

If in eyes: Rinse cautiously with water for several minutes.

Remove contact lens, if present and easy to do. Continue rinsing.

Do not rub affected areas.

If eye irritation persists: Get medical advice attention.

3. Composition/Information on Ingredients

| Hazardous Components | C.A.S. Number | Exposure Limits | % |
|------------------------------------|---------------|----------------------|------|
| Aluminum Oxide | 1344-28-1 | 10 mg/M ³ | < 65 |
| Glycerine | 56-81-5 | 10 mg/M ³ | < 50 |
| Hydrophobic Amorphous Fumed Silica | 68611-44-9 | 3 mg/M ³ | < 5 |

3. Hazard Identification

| Emergency Overview: Material may be irritating to eyes. No significant hazards for emergency responses are known. | | | | | |
|---|--|--|-----------------------------------|--|-----------------|
| 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 may cause slight transient (temporary) irritation. | Single & Repeated | Moderate | Irritation and possible corneal damage due to the fillers used in the product. | Not Applicable |
| Skin | Material may be an irritant after repeated and prolonged exposure. | Repeated | Mild | Irritation or possible allergic response. | Not Applicable |
| Inhalation | Vapors are minimal due to physical properties. | Not Applicable | Not Applicable | Not Applicable | Not Applicable |
| Ingestion | Material is probably not harmful if swallowed | Not Applicable | Mild | Not Applicable | Not Applicable |
| Other | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable |
| Medical Conditions Aggravated by Exposure Open sores and wounds of the skin. | | | | | |
| Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory. | | | | | |
| Potential Environmental Effects Do not allow to enter sewers/ surface or ground water. | | | | | |
| NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 0, Reactivity = 0 | | | | | |

4. First Aid Measures

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

| | | | |
|---|--|----------------|----------------|
| Skin | Immediately wash with soap and water and rinse thoroughly. | Not Applicable | Not Applicable |
| Inhalation | Supply fresh air, consult physician if symptoms persist. | Not Applicable | Not Applicable |
| Ingestion | If symptoms persist consult physician. Do not induce vomiting unless instructed to do so by medical personnel. | Not Applicable | Not Applicable |
| Other | Not Applicable | Not Applicable | Not Applicable |
| Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically. | | | |

5. Fire and Explosion Data

| | | | |
|---|---|--|-----------------------|
| Flashpoint Method: 390°F (199°C) for Glycerine. Pensky-Martin Closed Cup | Flammable (Explosive) Limits in Air LEL: Not Applicable UEL: Not Applicable | Autoignition Temperature: 698°F (370°C) | Other: Not Applicable |
| Flame Propagation or Burning Rate (for Solids) Not Applicable | Properties Contributing to Fire Intensity: Not Applicable | Flammability Classification: Not Applicable | |
| Extinguishing Media: CO ₂ , Water fog or fine spray, foam, carbon dioxide or alcohol resistant foams (ATC Type). | | 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: During a fire, smoke may contain glycerine in addition to unidentified toxic and/or irritating compounds. Hazardous combustion products may include but not limited to aldehydes, carbon monoxide and carbon dioxide. | | | |

6. Accidental Release Measures

| | | |
|--|--------------------------------------|--|
| Containment Techniques: Material is a high viscosity paste, but will flow somewhat. | | |
| Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container. | | |
| Evacuation Procedures: Not Applicable | Special Instructions: Not Applicable | Reporting Requirements: Not Applicable |

7. Handling and Storage

| |
|--|
| Handling Practices and Warnings: Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals. |
| Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Store away from food and beverages. Glycerine freezes at 64°F (18°C). Product should be kept above 64°F (18°C) but less than 130°F (54°C). |

8. Exposure Control / Personal Protection



| 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 |
| Occupational Exposure Limits: Not Applicable | | Engineering Controls: Not Applicable |

9. Physical and Chemical Characteristics

| | | |
|--|--|--|
| Appearance: Creamy viscous white paste. | Odor: Mild odor. | |
| Normal Physical State: High Viscosity Liquid (Paste) | Melting Point: Not Applicable | |
| Specific Gravity: 1.7 g/cm ³ | Solubility in Water: Partially soluble. | pH: Not Applicable |
| Vapor Pressure (mm Hg): Not Applicable | Vapor Density (AIR=1): Not Applicable | Evaporation Rate (Butyl Acetate =1): N A |
| Flashpoint Method: Not Applicable | Flammable (Explosive) Limits in Air LEL: Not Applicable UEL: Not Applicable | Autoignition Temperature: Not Applicable |
| Other: Not Applicable | | |

10. Stability and Reactivity Data

| | | |
|---|---------------------------------|--|
| Incompatibility (Materials to Avoid): Strong Oxidizing materials such as Sodium Hypochlorite or Hypochlorous Acid | | |
| Hazardous Products Produced During Decomposition: Acrolein. | | |
| Hazardous Polymerization: <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: For ingestion, the LD ₅₀ for glycerine in Rats is 17,000 – 27,000 mg/Kg. | | | | | |
| Emergency Overview: Material may be mildly irritating to eyes. | | | | | |
| 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 may cause slight transient (temporary) irritation. | Single & Repeated | Moderate | Irritation and possible corneal damage due to the fillers used in the product. | Not Applicable |

| | | | | | |
|---|--|----------------|----------------|---|----------------|
| Skin | Material may be an irritant after repeated and prolonged exposure. | Repeated | Mild | Irritation or possible allergic response. | Not Applicable |
| Inhalation | Vapors are minimal due to physical properties. | Not Applicable | Not Applicable | Not Applicable | Not Applicable |
| Ingestion | Material is probably not harmful if swallowed | Not Applicable | Mild | Not Applicable | Not Applicable |
| Other | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable |
| Medical Conditions Aggravated by Exposure Open sores and wounds of the skin. | | | | | |
| Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory. | | | | | |
| Potential Environmental Effects: 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. 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: CERCLA 103 Reportable Quantity: This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations

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

Section 302 Extremely Hazardous Substances (TPQ): None

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

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

International Regulations: Canadian Environmental Protection Act:

This product is a medical device and not subject to chemical notification requirements.

European Community Labeling: Not a dangerous preparation.

European Inventory of New and Existing Chemicals Substances (EINECS):

This product is a medical device and not subject to chemical notification requirements.

Other: Not Applicable

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.