DENTSPLY/International DENTSPLY/Caulk Safety Data Sheet

1. Identification

| Product Name | MSDS Code Number |
|--|---|
| POLYJEL [®] NF [™] Catalyst Paste Elastic Polyether Impression | 518002 |
| Material | |
| Trade Name & Synonyms | Date of Last Revision |
| POLYJEL® NF [™] Catalyst Paste Elastic Polyether Impression | 12/14/15 |
| 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 |
| Not Applicable | (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time) |
| Product Use (for Canada) | Emergency Telephone Number |
| Not Applicable | (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time) |

2. Hazard(s) Identification



WARNING CAUSES SKIN IRRITATION

Wash hands thoroughly after handling. Wear protective gloves.

IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/ attention. Take off contaminated clothing and wash before reuse.

3. Composition/Information on Ingredients

| Hazardous Components | C.A.S. Number | Exposure Limits | % |
|-----------------------------------|---------------|--------------------|------|
| Sulfonium Salt | Proprietary | Not Established | < 40 |
| Citric Ester | Proprietary | Not Established | < 40 |
| Silane Treated Silica | 68909-20-6 | Not Established | < 25 |
| Polyethylene-polypropylene Glycol | 9003-11-6 | Not Established | < 10 |
| Diatomaceous Earth | 68855-54-9 | 6 mg/M^3 | < 10 |

4. First Aid Measures

| Routes of Exposure | First Aid Instructions | Immediate Medical Attention | Delayed Effects |
|------------------------|---|-----------------------------|-----------------|
| Eye | Flush eyes with large amounts of water. | Not Applicable | Not Applicable |
| | If symptoms persist get medical attention. | | |
| Skin | If on skin wash with plenty of soap and water. If skin irritation occurs: get | Not Applicable | Not Applicable |
| | medical attention. Take off contaminated clothing and wash before reuse. | | |
| Inhalation | No first aid is anticipated. | Not Applicable | Not Applicable |
| Ingestion | No first aid is anticipated. | Not Applicable | Not Applicable |
| Other | Not Applicable | Not Applicable | Not Applicable |
| Note to Physicians (Tr | eating, Testing and Monitoring): Treat symptomatically. | | |

5. Fire Fighting Measures

| Flashpoint: Not Applicable | Flammable (Explosive) Limits in Air | Autoignition Temperature: | Other: Not | |
|---|--|------------------------------|------------|--|
| Flashpoint Method: Not Applicable | LEL: not determined UEL: not determined | Not determined | Applicable | |
| Flame Propagation or Burning Rate (for Solids): | Properties Contributing to Fire Intensity: Not | Flammability Classification: | | |
| Not Applicable | Applicable | Not Applicable | | |
| Extinguishing Media: Class B - CO ₂ , or dry chemical extinguishing powder. Extinguishing Media to Avoid: Water with full jet | | | | |
| Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices. Water should be used to keep fire-exposed | | | | |
| containers and surfaces cool. | | | | |
| Unusual Fire and Explosion Hazards: Not Applicable. | | | | |

Hazardous Decomposition Products: Thermal breakdown of this product during fire or very high heat conditions may evolve the following hazardous decomposition products. Carbon monoxide, carbon dioxide and irritating vapor or gases.

6. Accidental Release Measures

| L | Containment Techniques: Wear protective clothing. Scoop up spilled material and place in suitable labeled plastic or metal container. | | | |
|---|--|--|--|--|
| | Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing. Place material in suitable labeled plastic or metal container. Avoid gross skin contact to | | | |
| L | minimize the possibility of contact 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: Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals. Use with adequate ventilation. Avoid eye exposure. Avoid skin contact. Keep container closed.

Storage Practices and Warnings: Store away from heat. Store only in the original package. Store out of direct sunlight. Keep package tightly sealed. Store away from food and beverages.

8. Exposure Control / Personal Protection









| Ventilation: None required during normal intended use of this product | | | | |
|---|--|---------------------|--|--|
| Other Engineering Cont | Other Engineering Controls: Local ventilation if large amounts are used. | | | |
| Individual Protection | Personal Protective Equipment for Normal Use | Personal Protective | | |
| Measures | easures Equipment for Emergencie | | | |
| Eye/Face | Eye/Face Safety Glasses Not Applicable | | | |
| Skin | Skin The glove material has to be impermeable and resistant to the product. Not Appl | | | |
| Inhalation Not required when using clinically relevant quantities used in Dental office. Not Applic | | Not Applicable | | |
| Body Protection Protective work clothing Not Applicable | | | | |

9. Physical and Chemical Characteristics

| Appearance: Yellow paste. Odor: Slightly acrid odor. | | | | |
|---|--|---|---------------------|------------------------------------|
| Normal Physical State: Solid (high viscosity paste). | | Boiling Point: Not Determined Flash Point: Not Applicable | | Flash Point: Not Applicable |
| Specific Gravity: $\sim 1.1 - 1.4 \text{ g/cm}^2$ Solubility in Water: Not soluble. | | pH: Not Applicable. | | |
| Vapor Pressure (mm Hg): Not Determined Vapor Density (AIR=1): Not | | Determined | Evaporation Rate (I | Butyl Acetate =1): Approximately 1 |
| Other: Not Applicable | | | | |

10. Stability and Reactivity Data

| Incompatibility (Materials to Avoid): Excessive heat. | |
|---|---|
| Hazardous Products Produced During Decomposition: Thermal breakdown | of this product during fire or very high heat conditions may evolve the following |
| hazardous decomposition products. Carbon monoxide, carbon dioxide and irritating vapor or gases. | |
| Hazardous Polymerization: May Occur May Not Occur Conditions to Avoid: High Temperatures, ignition sources. | |
| Stability? ⊠Stable □Unstable | Conditions to Avoid: High Temperatures, ignition sources. |

11.Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data: Product may be a mild irritant to the skin and mucous membranes in susceptible persons. On the eye the product may have an irritating effect.

Emergency Overview: Material is irritating to eyes, respiratory system and skin. Routes of Single, Repeated, or Severity (Mild, Acute and Chronic Target Organ(s) Health Effect(s) Exposure Lifetime Exposure Moderate Signs and Symptoms Severe) Eye Material can cause irritation. Signs and Symptoms Mild Single Eye Irritation Yes may include redness, pain, and tearing. Skin Mild Single & Repeated Yes Contact with the skin during product use is not Irritation, reddening expected to result in significant irritation. of the skin. Inhalation No adverse health effects are expected. Not Applicable Not Applicable Not Applicable Not Applicable No adverse health effects are expected. Not Applicable Not Applicable Not Applicable Not Applicable Ingestion Other: CNS 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 = 1, Reactivity= 0 Specific Hazard = None

12.Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Not determined.

13.Disposal Considerations

Regulations: Dispose of completely cured (or Polymerized) wastes in a sanitary landfill. 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. RCRA P-Series: None listed, RCRA U-Series Not Regulated.

14.Transport Information

| Regulated for Shipping: No | Proper Shipping Name: Not Regulated | | Packing Group: Not Applicable |
|--|-------------------------------------|------------------------------|--|
| Do Changes in Quantities, packaging, or shipment | | Hazard Class: Not Applicable | UN Identification 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: None Listed. Report spills required under federal, state and local regulations

SARA Code: None Listed.

Section 312 Hazard Class: Fire Hazard: No, Pressure Hazard: No, Reactivity Hazard: No, Acute (Immediate Hazard): Yes, Chronic (Delayed Hazard): No,

Section 313 Toxic Chemicals: None Listed. This product does not contain any chemicals subject to Annual Release Reporting Requirements as per Section 313 of SARA Title III and 40 CFR Part 373.

Section 302 Extremely Hazardous Substances (TPQ): None

OSHA:

RCRA P-Series: None Listed.

RCRA U-Series Hazardous Waste Code: Not Listed.

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.

WGK (Water Danger/Protection) Not Applicable

Canada - DSL/NDSL Not Applicable

Canada – WHMIS Not Applicable

Canadian Ingredient Disclosure List: No chemicals are on the Canadian Ingredient Disclosure List.

<u>Canadian Environmental Protection Act:</u> This product is a medical device and not subject to chemical notification requirements.

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

Other: Not Applicable

16.Other Information

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex.

All components are synthetically produced; none are derived from animal products.

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific products features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer. For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

DENTSPLY/International DENTSPLY/Caulk Safety Data Sheet

518001

1. Identification

| Product Name | MSDS Code Number |
|---|---|
| POLYJEL [®] NF [™] Base Paste Elastic Polyether Impression Material | 518001 |
| Trade Name & Synonyms | Date of Last Revision |
| POLYJEL® NF [™] Base Paste Elastic Polyether Impression Material | 12/14/15 |
| Manufacturer: | Address |
| DENTSPLY Caulk | 38 West Clarke Avenue |
| | Milford DE 19963-1805 |
| | http://www.caulk.com |
| | http://www.dentsply.com |
| Grades or Minor Variant Identities | Information Telephone Number |
| Not Applicable | (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time) |
| Product Use (for Canada) | Emergency Telephone Number |
| Not Applicable | (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time) |

2. Hazard(s) Identification



WARNING

CAUSES SKIN IRRITATION

Wash hands thoroughly after handling. Wear protective gloves.

IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/ attention. Take off contaminated clothing and wash before reuse.

3. Composition/Information on Ingredients

| Hazardous Components | C.A.S. Number | Exposure Limits | % |
|---------------------------|---------------|--------------------|------|
| Polyether | Proprietary | Not Established | < 60 |
| Diatomaceous Earth | 68855-54-9 | 6 mg/M^3 | < 20 |
| Fatty Acids Triglycerides | Proprietary | Not Established | < 20 |
| Dibenzyl Toluene | Proprietary | Not Established | < 20 |

4. First Aid Measures

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|------------------------|---|-----------------------------|-----------------|
| Routes of Exposure | First Aid Instructions | Immediate Medical Attention | Delayed Effects |
| Eye | Flush eyes with large amounts of water. | Not Applicable | Not Applicable |
| | If symptoms persist get medical attention. | | |
| Skin | If on skin wash with plenty of soap and water. If skin irritation occurs: get | Not Applicable | Not Applicable |
| | medical attention. Take off contaminated clothing and wash before reuse. | | |
| Inhalation | No first aid is anticipated. | Not Applicable | Not Applicable |
| Ingestion | No first aid is anticipated. | Not Applicable | Not Applicable |
| Other | Not Applicable | Not Applicable | Not Applicable |
| Note to Physicians (Tr | reating, Testing and Monitoring): Treat symptomatically. | | |

5. Fire Fighting Measures

| 5 4 1 1 4 1 5 1 1 4 1 5 1 1 4 1 5 1 1 4 1 4 1 4 1 4 | | | | | |
|---|--|---|------------|--|--|
| Flashpoint: Not Applicable | Flammable (Explosive) Limits in Air | | Other: Not | | |
| Flashpoint Method: Not Applicable | cable LEL: not determined UEL: not determined | | Applicable | | |
| Flame Propagation or Burning Rate (for Solids): | Properties Contributing to Fire Intensity: Not | Flammability Classification: | | | |
| Not Applicable | Applicable | Not Applicable | | | |
| Extinguishing Media: Class B - CO ₂ , or dry chemical extinguishing powder. | | Extinguishing Media to Avoid: Water with full jet | | | |
| Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices. Water should be used to keep fire-exposed | | | | | |
| containers and surfaces cool. | | | | | |
| Unusual Fire and Explosion Hazards: Not Applicable. | | | | | |
| Hazardous Decomposition Products: Thermal breakdown of this product during fire or very high heat conditions may evolve the following hazardous decomposition | | | | | |
| products. Carbon monoxide, carbon dioxide and irritating vapor or gases. | | | | | |

6. Accidental Release Measures

Containment Techniques: Wear protective clothing. Scoop up spilled material and place in suitable labeled plastic or metal container.

Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing. Place material in suitable labeled plastic or metal container. Avoid gross skin contact to minimize the possibility of contact 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: Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals. Use with adequate ventilation. Avoid eye exposure. Avoid skin contact. Keep container closed.

Storage Practices and Warnings: Store away from heat. Store only in the original package. Store out of direct sunlight. Keep package tightly sealed. Store away from food and beverages.

8. Exposure Control / Personal Protection









| Ventilation: None required during normal intended use of this product | | | | |
|--|---|---------------------------|--|--|
| Other Engineering Controls: Local ventilation if large amounts are used. | | | | |
| Individual Protection | Personal Protective Equipment for Normal Use Personal Protective | | | |
| Measures | | 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 when using clinically relevant quantities used in Dental office. | Not Applicable | | |
| Body Protection | Protective work clothing | Not Applicable | | |

9. Physical and Chemical Characteristics

| V | | | | |
|--|----------------------------------|-------------------------------|-----------------------------|--|
| Appearance: Bluish-grey paste. | | Odor: Characteristic odor. | | |
| Normal Physical State: Solid (high viscosity paste). | | Boiling Point: Not Determined | Flash Point: Not Applicable | |
| Specific Gravity: ~ 1.0 – 1.2 g/cm ² | Solubility in Water: Not soluble | pH: Not Applicable | | |
| Vapor Pressure (mm Hg): Not Determined | | ate =1): Approximately 1 | | |
| Other: Not Applicable | | | | |

10. Stability and Reactivity Data

| Incompatibility (Materials to Avoid): Excessive heat. | | | |
|---|--|--|--|
| Hazardous Products Produced During Decomposition: Thermal breakdown of this product during fire or very high heat conditions may evolve the following | | | |
| hazardous decomposition products. Carbon monoxide, carbon dioxide and irritating vapor or gases. | | | |
| Hazardous Polymerization: May Occur May Not Occur Conditions to Avoid: High Temperatures, ignition sources. | | | |
| Stability? ☑ Stable ☐ Unstable ☐ Conditions to Avoid: High Temperatures, ignition sources. | | | |

11.Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data: Product may be a mild irritant to the skin and mucous membranes in susceptible persons. On the eye the product has an irritating effect.

Emergency Overview: Material is irritating to eyes, respiratory system and skin. Routes of Single, Repeated, or Severity (Mild, Acute and Chronic Target Organ(s) Signs and Symptoms Lifetime Exposure Exposure Moderate, Health Effect(s) Severe) Eye Material can cause irritation. Signs and Symptoms Single Mild Eye Irritation Yes may include redness, pain, and tearing. Contact with the skin during product use is not Single & Repeated Skin Mild Irritation, reddening Yes expected to result in significant irritation. of the skin. Inhalation No adverse health effects are expected. Not Applicable Not Applicable Not Applicable Not Applicable Ingestion No adverse health effects are expected. Not Applicable Not Applicable Not Applicable Not Applicable Not Applicable Other: CNS 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 = 1, Reactivity= 0 Specific Hazard = None

12. Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Not determined.

13.Disposal Considerations

Regulations: Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Dispose of contents/container as solid waste in a closed container. Dispose of contents/container in accordance with Federal, State and Local regulations.

Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container. RCRA P-Series: None Listed, RCRA U-Series: Not Regulated.

14.Transport Information

| Regulated for Shipping: No | Proper Shipping Name: Not Regulated | | Packing Group: Not Applicable |
|--|-------------------------------------|------------------------------|--|
| Do Changes in Quantities, packaging, or shipment | | Hazard Class: Not Applicable | UN Identification Number: Not Applicable |
| method change product classification? No | | | |

15.Regulatory Information

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U.S. Federal Regulations: CERCLA 103 Reportable Quantity: None Listed. Report spills required under federal, state and local regulations

SARA Code: None Listed.

Section 312 Hazard Class: Fire Hazard: No, Pressure Hazard: No, Reactivity Hazard: No, Acute (Immediate Hazard): Yes, Chronic (Delayed Hazard): No,

Section 313 Toxic Chemicals: None Listed. This product does not contain any chemicals subject to Annual Release Reporting Requirements as per Section 313 of SARA Title III and 40 CFR Part 373.

Section 302 Extremely Hazardous Substances (TPQ): None

OSHA:

RCRA P-Series: None Listed.

RCRA U-Series Hazardous Waste Code: Not Listed.

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.

WGK (Water Danger/Protection) Not Applicable

<u>Canada – DSL/NDSL</u> Not Applicable

<u>Canada – WHMIS</u> Not Applicable

Canadian Ingredient Disclosure List: No chemicals are on the Canadian Ingredient Disclosure List.

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

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

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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.