

SAFETY DATA SHEET

NAME OF PRODUCT: PRELINE™ Base Paste

FILE NO.: SDS5016B

SDS DATE: 06/19/2014

SECTION 1: IDENTIFICATION

PRODUCT NAME: PRELINE Base Paste
PRODUCT CODES: 100-5016, 101-0586
IDENTIFIED USES: Dentistry
USES ADVISED AGAINST: Non-dental use
DISTRIBUTED BY: Henry Schein, Inc.
ADDRESS: 135 Duryea Road
CITY, STATE, ZIP: Melville, NY 11747
TELEPHONE: 1-800-472-4346
EMERGENCY: Chemtrec 1-800-424-9300
DATE PREPARED: 06/19/2014

SECTION 2: HAZARDS IDENTIFICATION

CLASSIFICATION: Skin irritation (Category 3)
 Eye irritation (Category 2B)
 Chronic aquatic toxicity (Category 4)

LABELING: FDA regulated device - exempt from Regulation (US) 29 CFR 1910.1200.

PICTOGRAM: None

SIGNAL WORD: Warning

HAZARD STATEMENTS:
 H316 Causes mild skin irritation.
 H320 Causes eye irritation.
 H413 May cause long lasting harmful effects to aquatic life.

PRECAUTIONARY STATEMENTS:
 P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P234 Keep only in original container.
 P235+P410 Keep cool. Protect from sunlight.
 P261 Avoid breathing dust/fume/gas/mist/vapors/spray.
 P264 Wash thoroughly after handling.
 P270 Do not eat, drink or smoke when using this product.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
 P301+P330 IF SWALLOWED: Rinse mouth.
 P302+P352 IF ON SKIN: Wash with plenty of soap and water.
 P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P308+P313 IF exposed or concerned: Get medical advice/attention.
 P332+P313 If skin irritation occurs: Get medical advice/attention.
 P337+P313 If eye irritation persists: Get medical advice/attention.
 P342+P313 If experiencing respiratory symptoms: Get medical advice/attention.
 P391 Collect spillage.
 P402 Store in a dry place.
 P403+P233 Store in a well-ventilated place. Keep container tightly closed.
 P501 Dispose of contents/container to an approved waste disposal plant.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

COMPONENT	CAS NO.	%WT	OSHA PEL - TWA	ACGIH TLV - TWA	CLASSIFICATION
Zinc Oxide	1314-13-2	5-15	10 mg/m ³ (T); 5 mg/m ³ (R)	2 mg/m ³ (R)	Aquatic Acute 1; Aquatic Chronic 1; H410

For full text of H-statements mentioned in this section, see section 16.

SECTION 4: FIRST-AID MEASURES

INHALATION: Move person into fresh air. If not breathing, give artificial respiration. If symptoms persist, get medical attention.

SKIN: Wash off with soap and plenty of water. Get medical attention if irritation develops and persists.

EYE: Rinse thoroughly with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

INGESTION: Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

SECTION 5: FIRE-FIGHTING MEASURES

SUITABLE EXTINGUISHING MEDIA: Water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
HAZARDOUS DECOMPOSITION PRODUCTS: Oxides of carbon, calcium, tungsten, phosphorus and zinc.
SPECIAL HAZARDS: No further relevant information available.
ADVICE FOR FIREFIGHTERS: Wear self contained breathing apparatus for firefighting if necessary.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: Use personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.
ENVIRONMENTAL PRECAUTIONS: Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.
CONTAINMENT AND CLEANUP: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Place in suitable, closed container for disposal according to official regulations.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING: 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. Avoid contact with the eyes and skin. Avoid inhalation of vapor or mist. Keep away from foodstuffs, beverages and animal feed.
CONDITIONS FOR SAFE STORAGE: Store only in the original package. Keep container tightly sealed in a dry and well-ventilated place. Protect from heat and direct sunlight. Store away from food and beverages.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: Handle in accordance with good industrial hygiene and safety practice. Use with adequate general or local exhaust ventilation to maintain exposure levels below the occupational exposure limits. Local exhaust ventilation is preferred since it prevents contamination dispersion into the work area by controlling it at its source. Provide eyewash and safety shower if contact or splash hazard exists. Wash hands before breaks and at the end of work.
EYE/FACE PROTECTION: Safety glasses.
SKIN PROTECTION: Glove material impermeable and resistant to the product.
BODY PROTECTION: Protective work clothing.
RESPIRATORY PROTECTION: NIOSH (US) or CEN (EU) approved respirators and components.
ENVIRONMENTAL EXPOSURE: Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/COLOR: Tan Paste
ODOR: Wintergreen
RELATIVE DENSITY (H₂O=1.0): 1.98 g/cm³
WATER SOLUBILITY: Not soluble

SECTION 10: STABILITY AND REACTIVITY

CHEMICAL STABILITY: Stable under recommended storage conditions.
HAZARDOUS REACTIONS: No further relevant information available.
CONDITIONS TO AVOID: Heat. Humidity.
INCOMPATIBLE MATERIALS: Strong oxidizing agents.
HAZARDOUS DECOMPOSITION PRODUCTS: Oxides of carbon, calcium, tungsten, phosphorus and zinc.

SECTION 11: TOXICOLOGICAL INFORMATION

POTENTIAL HEALTH EFFECTS: **EYES:** May cause eye irritation with redness, tearing and stinging.
SKIN: May cause skin irritation with redness, swelling and itching. Prolonged skin contact may cause dermatitis.
INGESTION: May cause mucous membrane and gastrointestinal irritation with nausea, vomiting and diarrhea.
INHALATION: No health effects expected.
CARCINOGENICITY: **OSHA:** No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or possible carcinogen by OSHA.

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ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

SECTION 12: ECOLOGICAL INFORMATION

ADVERSE EFFECTS: An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. May cause long lasting harmful effects to aquatic life. Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

PRODUCT: Offer surplus and non-recyclable solutions to a licensed disposal company. Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Disposal must be made according to official regulations.

CONTAMINATED PACKAGING: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

UN NUMBER: N/A

PROPER SHIPPING NAME: N/A

HAZARD CLASS: N/A

PACKING GROUP: N/A

LABEL STATEMENT: N/A

SECTION 15: REGULATORY INFORMATION

US FEDERAL REGULATIONS

TSCA This product is an FDA regulated device and not subject to TSCA regulations.

CERCLA This product is an FDA regulated device and not subject to reporting requirements. There may be specific reporting requirements at the local, regional, or state level.

SARA 313 TOXIC CHEMICALS The following components are subject to reporting levels established by SARA Title III, Section 313 (40 CFR 372): *Zinc Oxide, CAS NO. 1314-13-2*.

SARA 311/312 HAZARDS This product is an FDA regulated device and not subject to reporting requirements.

US STATE REGULATIONS

CALIFORNIA PROPOSITION 65: This product may contain a chemical known to the State of California to cause cancer and/or reproductive toxicity.

INTERNATIONAL REGULATIONS

CANADIAN ENVIRONMENTAL PROTECTION ACT: This product is a medical device and not subject to chemical notification requirements.

EUROPEAN INVENTORY OF EXISTING COMMERCIAL CHEMICAL SUBSTANCES (EINECS): This product is a medical device and not subject to chemical notification requirements.

SECTION 16: OTHER INFORMATION

FULL TEXT OF H STATEMENTS REFERRED TO UNDER SECTION 3

Aquatic Acute Acute aquatic toxicity
Aquatic Chronic Chronic aquatic toxicity
H410 Very toxic to aquatic life with long lasting effects.

NFPA RATING

Health Hazard 1
Fire Hazard 0
Reactivity Hazard 0

PREPARED BY: SS

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 HENRY SCHEIN®
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PREPARATION INFORMATION: This SDS was prepared in accordance with the requirements of the OSHA Hazard Communication Standard (29 CFR 1910.1200) and is to be used only for this product.

DISCLAIMER: To the best of our knowledge, the information contained herein is accurate. However, Henry Schein, Inc. does not assume any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown health hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

SECTION 1: IDENTIFICATION

PRODUCT NAME: PRELINE Catalyst Paste
PRODUCT CODES: 100-5016, 101-0586
IDENTIFIED USES: Dentistry
USES ADVISED AGAINST: Non-dental use
DISTRIBUTED BY: Henry Schein, Inc.
ADDRESS: 135 Duryea Road
CITY, STATE, ZIP: Melville, NY 11747
TELEPHONE: 1-800-472-4346
EMERGENCY: Chemtrec 1-800-424-9300
DATE PREPARED: 06/19/2014

SECTION 2: HAZARDS IDENTIFICATION

CLASSIFICATION: Skin irritation (Category 2)
 Serious eye damage (Category 1)
 Acute aquatic toxicity (Category 3)
 Chronic aquatic toxicity (Category 3)
LABELING: FDA regulated device - exempt from Regulation (US) 29 CFR 1910.1200.

PICTOGRAM:


SIGNAL WORD: Danger

HAZARD STATEMENTS:

H315 Causes skin irritation.
 H318 Causes serious eye damage.
 H412 Harmful to aquatic life with long lasting effects.
PRECAUTIONARY STATEMENTS:
 P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P234 Keep only in original container.
 P235+P410 Keep cool. Protect from sunlight.
 P261 Avoid breathing dust/fume/gas/mist/vapors/spray.
 P264 Wash thoroughly after handling.
 P270 Do not eat, drink or smoke when using this product.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
 P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
 P302+P352 IF ON SKIN: Wash with plenty of soap and water.
 P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P308+P313 IF exposed or concerned: Get medical advice/attention.
 P310 Immediately call a POISON CENTER or doctor/ physician.
 P321 Specific treatment (see supplemental first aid instructions on this label).
 P332+P313 If skin irritation occurs: Get medical advice/attention.
 P337+P313 If eye irritation persists: Get medical advice/attention.
 P342+P313 If experiencing respiratory symptoms: Get medical advice/attention.
 P362 Take off contaminated clothing and wash before reuse.
 P391 Collect spillage.
 P402 Store in a dry place.
 P403+P233 Store in a well-ventilated place. Keep container tightly closed.
 P501 Dispose of contents/container to an approved waste disposal plant.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

COMPONENT	CAS NO.	%WT	OSHA PEL - TWA	ACGIH TLV - TWA	CLASSIFICATION
Calcium Hydroxide	1305-62-0	45-55	15 mg/m ³ (T); 5 mg/m ³ (R)	5 mg/m ³	Skin Irrit. 2; Eye Dam. 1; STOT SE 3; Aquatic Acute 3; Aquatic Chronic 3; H315, H318, H335, H412
Zinc Oxide	1314-13-2	5-15	10 mg/m ³ (T); 5 mg/m ³ (R)	2 mg/m ³ (R)	Aquatic Acute 1; Aquatic Chronic 1; H410
Titanium Dioxide	13463-67-7	2.5-10	15 mg/m ³ (T)	10 mg/m ³	Acute Tox. 4; Skin Irrit. 2; Eye Irrit. 2A; STOT SE 3; H315, H319, H332, H335

For full text of H-statements mentioned in this section, see section 16.

SECTION 4: FIRST-AID MEASURES

INHALATION:	Move person into fresh air. If not breathing, give artificial respiration. If symptoms persist, get medical attention.
SKIN:	Wash off with soap and plenty of water. Get medical attention if irritation develops and persists.
EYE:	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Continue rinsing eyes during transport to hospital.
INGESTION:	Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

SECTION 5: FIRE-FIGHTING MEASURES

SUITABLE EXTINGUISHING MEDIA:	Water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
HAZARDOUS DECOMPOSITION PRODUCTS:	Oxides of carbon, calcium and zinc.
SPECIAL HAZARDS:	No further relevant information available.
ADVICE FOR FIREFIGHTERS:	Wear self contained breathing apparatus for firefighting if necessary.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:	Use personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.
ENVIRONMENTAL PRECAUTIONS:	Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.
CONTAINMENT AND CLEANUP:	Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Place in suitable, closed container for disposal according to official regulations.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING:	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. Avoid contact with the eyes and skin. Avoid inhalation of vapor or mist. Keep away from foodstuffs, beverages and animal feed.
CONDITIONS FOR SAFE STORAGE:	Store only in the original package. Keep container tightly sealed in a dry and well-ventilated place. Protect from heat and direct sunlight. Store away from food and beverages.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS:	Handle in accordance with good industrial hygiene and safety practice. Use with adequate general or local exhaust ventilation to maintain exposure levels below the occupational exposure limits. Local exhaust ventilation is preferred since it prevents contamination dispersion into the work area by controlling it at its source. Provide eyewash and safety shower if contact or splash hazard exists. Wash hands before breaks and at the end of work.
EYE/FACE PROTECTION:	Safety glasses.
SKIN PROTECTION:	Glove material impermeable and resistant to the product.
BODY PROTECTION:	Protective work clothing.
RESPIRATORY PROTECTION:	NIOSH (US) or CEN (EU) approved respirators and components.
ENVIRONMENTAL EXPOSURE:	Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/COLOR:	White Paste
ODOR:	No odor
pH:	Alkaline
RELATIVE DENSITY (H₂O=1.0):	1.82 g/cm ³
WATER SOLUBILITY:	Not soluble

SECTION 10: STABILITY AND REACTIVITY

CHEMICAL STABILITY:	Stable under recommended storage conditions.
HAZARDOUS REACTIONS:	No further relevant information available.
CONDITIONS TO AVOID:	Heat. Humidity.
INCOMPATIBLE MATERIALS:	Strong acids, strong bases and strong oxidizing agents.

NAME OF PRODUCT: PRELINE™ Catalyst Paste

HAZARDOUS DECOMPOSITION PRODUCTS: Oxides of carbon, calcium and zinc.

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SECTION 11: TOXICOLOGICAL INFORMATION

POTENTIAL HEALTH EFFECTS: **EYES:** May cause eye irritation and possible corneal damage due to the caustic nature of ingredient used in the product.
SKIN: May cause skin irritation or possible allergic response.
INGESTION: May cause mucous membrane and gastrointestinal irritation due to the caustic nature of ingredients used in the product.
INHALATION: No health effects expected.

CARCINOGENICITY: **OSHA:** No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or possible carcinogen by OSHA.
ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
IARC: Titanium dioxide is identified as a possible human carcinogen by IARC.

SECTION 12: ECOLOGICAL INFORMATION

ADVERSE EFFECTS: An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Harmful to aquatic life with long lasting effects. Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

PRODUCT: Offer surplus and non-recyclable solutions to a licensed disposal company. Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Disposal must be made according to official regulations.

CONTAMINATED PACKAGING: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

UN NUMBER: N/A
PROPER SHIPPING NAME: N/A
HAZARD CLASS: N/A
PACKING GROUP: N/A
LABEL STATEMENT: N/A

SECTION 15: REGULATORY INFORMATION

US FEDERAL REGULATIONS

TSCA This product is an FDA regulated device and not subject to TSCA regulations.
CERCLA This product is an FDA regulated device and not subject to reporting requirements. There may be specific reporting requirements at the local, regional, or state level.

SARA 313 TOXIC CHEMICALS The following components are subject to reporting levels established by SARA Title III, Section 313 (40 CFR 372): *Zinc Oxide, CAS NO. 1314-13-2*.

SARA 311/312 HAZARDS This product is an FDA regulated device and not subject to reporting requirements.

US STATE REGULATIONS

CALIFORNIA PROPOSITION 65: This product may contain a chemical known to the State of California to cause cancer and/or reproductive toxicity.

INTERNATIONAL REGULATIONS

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SECTION 16: OTHER INFORMATION

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FULL TEXT OF H STATEMENTS REFERRED TO UNDER SECTION 3

Acute Tox.	Acute toxicity
Aquatic Acute	Acute aquatic toxicity
Aquatic Chronic	Chronic aquatic toxicity
Eye Dam.	Serious eye damage
Eye Irrit.	Eye irritation
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
Skin Irrit.	Skin irritation
STOT SE	Specific target organ toxicity – single exposure

NFPA RATING

Health Hazard	2
Fire Hazard	0
Reactivity Hazard	0

PREPARATION INFORMATION: This SDS was prepared in accordance with the requirements of the OSHA Hazard Communication Standard (29 CFR 1910.1200) and is to be used only for this product.

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