



Safety Data Sheet: Dazzle Prophy Paste

SECTION 1: IDENTIFICATION

Product Name: Dazzle Prophy Paste
 Catalog Numbers: Assorted Flavors
 Assorted Grits
 Product Classification: Prophylaxis Paste
 Active Ingredient: Sodium Fluoride
 Manufactured By: JP Solutions Brands
 618 Corporate Way Unit 1
 Valley Cottage, NY 10989
 Telephone: 1-845-589-0215
 Emergency Number: Chemtrec 1-800-424-9300
 Date Prepared: August 28, 2017
 Supersedes Date: New issue.
 Product Use: For cleaning and polishing procedures as a part of a professionally administered prophylaxis treatment.

SECTION 2: HAZARDS IDENTIFICATION

GHS Classification:

Health	Environmental	Physical
Acute Toxicity Category 4 (H302)	Not Hazardous	Not Hazardous

EU Classification: Harmful (Xn) R22

Label Elements:



Signal Word: Warning (Contains Sodium Fluoride)

Other Hazards: None known.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous Components	CAS #	EINECS #	Classification	WT %*
Sodium Fluoride	7681-49-4	231-667-8	T, Xi R25, R32, R36/38 Acute Toxicity Category 3, H301 Eye Irritant Category 2, H319 Skin Irritation Category 2, H315 EUH032	1% - 5%
Sodium Silicate	1344-09-8	215-687-4	Xi R36/37/38 Eye Irritant Category 2, H319 Skin Irritation Category 2, H315 STOT SE Category 3, H335	1% - 5%
Glycerin	56-81-5	200-289-5	Not Applicable	30% - 40%
Pumice	1332-09-8	Not Listed	Not Applicable	45% - 65%

*The exact weight percentages are being withheld as a trade secret.



SECTION 4: FIRST AID MEASURES

Description of First Aid Measures:

- Eye Contact:** Flush eyes with large amounts of water, including under eyelids. If signs/symptoms persist, seek medical attention.
- Skin Contact:** Wash thoroughly with soap and water. Remove contaminated clothing and launder before re-use. If signs/symptoms persist, seek medical attention.
- Inhalation:** Move to fresh air. If having difficulty breathing, administer oxygen. If signs/symptoms persist, seek medical attention.
- Ingestion:** Do not induce vomiting. If conscious, rinse mouth out and give copious amount of milk or water (if milk isn't available) to dilute contents of stomach. Never give anything by mouth to an unconscious or convulsing person. Seek medical attention if you feel unwell.

Most Important Symptoms and Effects, Both Acute and Delayed:

Direct eye contact may cause eye irritation. Prolonged skin contact may cause irritation. Harmful if swallowed. Prolonged inhalation of dusts from dried product may cause lung irritation and damage. Prolonged over exposures to sodium fluoride may cause fluorosis with symptoms of joint pain, limited mobility, brittle bones, calcification of ligaments, bone and teeth abnormalities and mottles tooth enamel.

Indication of Any Immediate Medical Attention and Special Treatment Needed:

If large quantities of this product has been ingested (10g for children under the age of 12, and 100g from adults), follow the ingestion first aid measures. Above, and seek medical attention.

Note to Physicians (Treatment, Testing, and Monitoring):

Treat symptomatically.

SECTION 5: FIRE FIGHTING MEASURES

- Extinguishing Media:** Suitable extinguishing material for the surrounding fire should be used.
- Firing Fighting Instruction:** Use water to cool fire-exposed containers and surrounding area. Fight fire from a safe distance, or from a protected area.
- Unusual Hazards:** During a fire, irritating or highly toxic gases may be generated by thermal decomposition, such as: carbon monoxide and carbon dioxide. If potential for exposure, wear complete personal protective equipment, including: an approved positive pressure self-contained breathing apparatus.



Recommended Protective Equipment for Fire Fighters:

Eyes/Face	Hands	Respiratory	Thermal
			

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures:

Avoid contact with eyes and avoid prolonged contact with skin. Do not breathe dust, mist, or vapors. Wear appropriate protective clothing as described in Section 8.

Recommended Personal Protective Equipment for Containment and Clean-Up:

- Eyes/Face:** None Anticipated.
- Hands:** None Anticipated.
- Respiratory:** None Anticipated.
- Skin:** None Anticipated.

Environmental Precautions:

Report releases as required by local, state, and national authorities.

Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

Handling: Avoid contact with eyes, skin, and clothing. Do not breathe dust, mist, or vapors. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use. Do not reuse containers. Empty containers retain product residues that can be hazardous. Follow all SDS precautions when handling empty containers.

Storage: Store in a cool, dry, well ventilated area away from heat, sparks, flame, and direct sunlight. Do not store above 77°F. Keep in original container provided by manufacturer.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:

Hazardous Components	Country	Limits
Sodium Fluoride	United States	5mg/m ³ (Respirable Fraction) 15mg/m ³ (Total Dust) TWA OSHA PEL (As Mist)
	Germany	1 mg/m ³ TGIH TLV 4mg/m ³ STEL DFG MAK (Inhalable, Skin)
	United Kingdom	2.5mg/m ³ TWA UK OEL
	European Union	2.5mg/m ³ TWA EU OEL



Hazardous Components	Country	Limits
Sodium Silicate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Glycerin	United States	5mg/m ³ (Respirable Fraction) 15mg/m ³ (Total Dust) TWA OSHA PEL (As Mist)
	Germany	50 mg/m ³ TWA 100mg/m ³ STEL DFG MAK (Inhalable)
	United Kingdom	10mg/m ³ TWA UK OEL
	European Union	10mg/m ³ TWA (Belgium)
Pumice	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established

Engineering Controls: General exhaust is adequate under normal operating conditions.

Eye/Face Protection: Safety glasses/goggles, splash shields, or eyeglasses are recommended when handling. Ensure an eye-wash station is on-hand.

Skin Protection: No special equipment for minor exposure (i.e. when handling small quantities), but, it is recommended that impermeable clothing (gloves, apron, boots, or whole body suit) to prevent any contact with this product.

Respiratory Protection: In case of insufficient ventilation, wear suitable respiratory equipment with particulate cartridges. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practices.

Thermal Protection: None required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Abrasive dispersion of pumice in a paste in various grits, colors, and flavors.	Explosive Limits:	LEL: Not Applicable UEL: Not Applicable
Odor:	Characteristic of the flavor	Vapor Pressure (mmHg):	Not Determined
Odor Threshold:	Not Determined	Vapor Density:	Not Determined
pH:	7 – 10	Relative Density:	Not Determined
Melting/Freezing Point:	Not Determined	Solubility:	Slightly soluble in water
Flash Point:	Not Applicable	Partition Coefficient: n-Octanol/Water:	Not Determined
Evaporation Rate:	Not Determined	Auto-Ignition Temperature:	Not Applicable
Explosive Properties:	Not Explosive	Oxidizing Properties:	Not an Oxidizer
Flammability (Solid, Gas):	Not Applicable	Viscosity:	Not Determined

Other Information: % Volatile by Volume: <10%



SECTION 10: STABILITY AND REACTIVITY

Reactivity:

None known.

Chemical Stability:

Stable under normal storage and handling conditions.

Possibility of Hazardous Reactions:

Hazardous polymerization will not occur. Contact with acids liberate very toxic gases. Contact with acids may form hydrogen fluoride.

Conditions to Avoid:

Avoid excessive heat sources and direct sunlight.

Incompatible Materials:

Avoid oxidizing agents and acids.

Hazardous Decomposition Products:

Decomposition may release carbon monoxide or carbon dioxide.

SECTION 11: TOXICOLOGY INFORMATION

Information on Toxicological Effects:

Potential Health Effects:

Eyes:

Direct contact may cause irritation with redness and tearing. Injury may occur from mechanical irritation.

Skin:

Prolonged skin contact may cause irritation.

Ingestion:

Harmful if swallowed. May cause salivation, nausea, vomiting. Ingestion of large quantities may cause abdominal pain, weakness, tremor, spasm, or convulsion.

Inhalation:

No adverse effects are expected under normal use conditions.

Chronic Health Effects:

Repeated excessive exposures to glycerin may cause fat levels in the blood and damage to the kidney and liver. Prolonged overexposure to sodium fluoride may cause cardiac disorders, damage to the kidneys and brain, and fluorosis with symptoms of joint pain, limited mobility, brittle bones, calcification of ligaments, bone and teeth abnormalities, and mottled tooth enamel.

Irritation:

Sodium Fluoride is highly irritating to not irritating in rabbit skin. High irritating to moderately irritating in rabbit eyes.

Corrosivity:

This product is not considered corrosive.

Sensitization:

No data is available. This product is not expected to cause sensitization.



Carcinogenicity:

Sodium Fluoride: A 2-year study in rats found a weak, equivocal fluoride-related increase in the occurrence of osteosarcomas in male rats, and no evidence of carcinogenicity in female rats or male or female mice. The weight of the evidence indicates that fluoridation of water does not increase the risk of developing cancer. IARC has determined that the carcinogenicity of fluoride to humans is not classifiable. None of the other components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH, or the EU CLP. Glycerin: No increase in tumor incidence was found in a 2-year oral feeding study with rats at doses 5 and 10 g/kg.

Mutagenicity:

Sodium Fluoride: Negative in the AMES test, but was positive in a mouse lymphoma cells assay. Sodium Fluoride did not induce DNA strand breaks in testicular cells of rats treated in-vivo and did not cause chromosomal aberrations in bone marrow or testicular cells or sister chromatid exchanges in bone marrow cells of mice treated in-vivo. Glycerin: Negative in AMES, in-vitro sister chromatid exchange and unscheduled DNA synthesis.

Medical Conditions Aggravated by Exposure:

Individuals with pre-existing eye or skin disease, or those with allergies to any of the ingredients in these products, may be at an increased risk from exposure.

Acute Toxicity Data:

Sodium Fluoride: Oral Rat LD50 – 32mg/kg

Sodium Silicate: Oral Rat LC50 1960mg/kg; Skin Rabbit LD50 - >460mg/kg

Glycerin: Oral Rabbit LD50 - >12,600mg/kg, Skin Rabbit LD50 - >10,000mg/kg; Inhalation Rat LC50 - >570mg/m³/1hr

Pumice: No toxicity data available

Reproductive Toxicity Data:

Sodium Fluoride: In a 75-day reproductive study with rats, dose of 4.5ppm and 9.0ppm show a significant decrease in sperm count, sperm motility, sperm viability and sperm function. However, other animal studies, including two-generation studies, have not found alterations in serum hormone levels in male rats, testicular histopathology, sperm morphology, or fertility. None of the available laboratory animal studies examined reproductive toxicity at low fluoride doses. The inadequate human studies and conflicting animal studies do not allow for an assessment of the potential of fluoride to induce reproductive effects in humans. Animal studies have not found increases in the incidences of birth defects in the absence of maternal toxicity; at doses that caused maternal toxicity (decreases in body weight gain and food consumption), increases in abnormalities were found. Glycerin: No effects were observed in a two-generation study at doses of 0.2mg/kg/day. No developmental effects were observed in rabbits administered up to 1,180mg/kg or in rats or mice administered up to 1,310mg/kg.

Single Target Organ Toxicity (STOT):

Single Exposure:

Sodium Fluoride: In a human exposure study, adults were given 250mg. Effects included nausea, vomiting, epigastric distress, salivation and itching of the hands and feet. In an acute study, dogs were infused with an acute dose of 36mg/kg. Death occurred in less than 65 minutes. Principal effects included a decline in blood pressure, heart rate, central nervous system activity, vomiting and defecation. Glycerin: When placed into the eye of a rabbit, glycerin will cause an inflammatory reaction, edema of the cornea and damage of the endothelial cells.



Repeated Exposure:

Sodium Fluoride: Brain, liver, kidneys and muscles demonstrate significant changes in essential trace element levels in adult female mice given 30ppm, 60ppm and 120ppm sodium fluoride in drinking water. Rats exposed to sodium fluoride in drinking water for two months developed thyroid effects; OAEL 0.5mg/kg/day. Mice exposed to sodium fluoride in drinking water for four weeks showed increased bone formation. LOAEL 0.8mg/kg/day. Glycerin: In a 13-week sub-chronic inhalation study with rates, glycerin was found to cause mild irritation of mucous membranes. In a two-year study in rats, no adverse effects were found in animals with 20% glycerin in their feed.

SECTION 12: ECOLOGICAL INFORMATION

Toxicity:

Sodium Fluoride: 96-hr LC50 Oncorhynchus mykiss (Rainbow Trout) – 83.7mg/L; 48-hr EC50 Daphnia Magna – 98mg/L

Sodium Silicate: 96-hr LC50 Zebra Fish – 3185mg/L; 96-hr EC50 Daphnia Magna – 216mg/L

Glycerin: 24-hr LC50 Goldfish - >5000mg/L; 48-hr EC50 Daphnia Magna – 10,000mg/L

Persistence and Degradability:

Glycerin is readily biodegradable (96% in 24 hours). Biodegradability does not apply to inorganic compounds.

Bio-accumulative Potential:

Glycerin is not expected to bioconcentrate in fish and aquatic organisms.

Mobility in Soil:

Glycerin: Very high mobility rate in soil.

Result of PBT and vPvB Assessment:

Not applicable.

Other Adverse Effects:

No adverse effects are expected.

SECTION 13: DISPOSAL CONSIDERATION

Dispose of in compliance with governmental regulations.

Empty containers retain product residuals that can be hazardous. Follow all SDS precautions when handling empty containers.

SECTION 14: TRANSPORTATION INFORMATION

	UN Number	UN Proper Shipping Name	Hazard Class(s)	Packing Group	Environmental Hazards
DOT	None	Not Regulated	None	None	Not applicable
ADR (road)	None	Not Regulated	None	None	Not applicable
RID (rail)	None	Not Regulated	None	None	Not applicable
IMDG (sea)	None	Not Regulated	None	None	Not applicable
IATA/ICAO (air)	None	Not Regulated	None	None	Not applicable



SECTION 15: REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

U.S. Federal Regulations:

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product has a Reportable Quantity (RQ) of 20,000 pounds (based on the RQ of 1,000 pounds for Sodium Fluoride present at 1% - 5%). Report spills required under federal, state and local regulations.

Toxic Substances Control Act (TSCA): This product is a medical device and not subject to chemical notification requirements.

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

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

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

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

Immediate Hazard: Yes Pressure Hazard: No

Delayed Hazard: No Reactivity Hazard: No

Fire Hazard: No

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372): None.

State Regulations:

California: This product does not contain any substances known to the state of California to cause cancer and/or reproductive toxicity.

International Regulations:

Canadian Workplace Hazardous Materials Information System (WHMIS): This product is a medical device and not subject to WHMIS.

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



Labeling According to EC Directives – 1272/2008 (CLP) and 1999/45/EC (items in parenthesis relate to 1999/45/EC)

European Community:



- DANGER SYMBOLS: **GHS07 (Xi)** – *Warning/Irritant*
- HAZARD STATEMENTS: **H302**, Harmful if swallowed; **H315**, Causes skin irritation; **H319**, Causes serious eye irritation
- PRECAUTIONARY STATEMENTS: See Section 16

SECTION 16: OTHER INFORMATION

EU Classes and Risk/Safety Phases for Referenced Ingredients (See Section 2)

Danger Symbols:

GHS07 – Warning/Irritant



Hazard Statements:

R25 – Harmful if swallowed
R32 – Contact with acids liberates toxic gas
R36/37/38 – Irritating to eyes, respiratory system, and skin

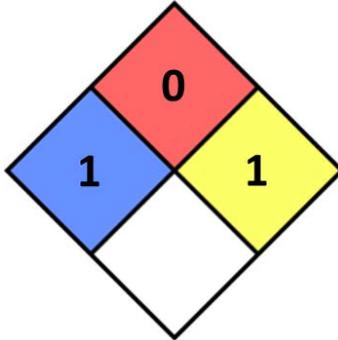
Precautionary Statements:

P102 – Keep out of reach of children
P264 – Wash hands after use, rinse oral cavity and expectorate fluid
P270 – Do not eat, drink, or smoke while using this product
P280 – Wear protective gloves/protective clothing/eye protection/face protection
P330 – Rinse mouth
P301+P312 – IF SWALLOWED: Call a POISON CENTER or a medical professional if you feel unwell
P302+P352 – IF ON SKIN: Wash with plenty of water
P332+P313 – If skin irritation occurs: Get medical advice/attention
P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing
P337+P313 – If eye irritation persists get medical advice/attention
P309+314 (S45) – If exposed, or you feel unwell, seek medical advice/attention



Hazard Rating System (Pictograms)

NFPA:



HMIS:



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