

**Section 1 – Identification**

**Product Name:** Primo® Shield 5% Sodium Fluoride Varnish      **Manufactured for:** Primo Dental Products.  
 www.primodentalproducts.com

**Active Ingredient:** Sodium Fluoride      **Information Contacts:** (888) 448-4274

**Emergency Phone Numbers:** US & Canada: (877) 833-3725

**Family:** Fluoride Treatment  
**Product Use:** Professional Dental Preventive Care  
**Product #:** Various

**Section 2 – Hazards Identification**

**Health:**  
 Acute Toxicity – Category 4 – H302 – Harmful if swallowed  
 Skin Irritant – Category 2 – H315 – Causes skin irritation  
 Eye Irritant – Category 2B – H320 – Causes eye irritation  
 Exposure – Category 3 – H335-336 – May cause respiratory irritation, May cause drowsiness or dizziness

**Environmental:**  
 Non-Hazardous

**Physical:**  
 Flammable Liquid – Category 3 – H225 – Highly flammable liquid and vapor

**Label Elements:**  
**GHS Label Elements:**  
 The product is classified and labeled according to the Globally Harmonized System (GHS).  
**Hazard Pictograms:**



**Section 3 – Composition/Information on Ingredients**

Chemical Identity	CAS Numbers	EINECS#	Substance Classification 67/548/EEC (EC) No. 1272/2008	%
Sodium Fluoride	7681-49-4	231-667-8	Acute Toxicity – Category 4 – H302 Skin Irritant – Category 2 – H315 Eye Irritant – Category 2B – H320 Exposure – Category 3 – H335-336	5%
Ethanol	64-17-5	200-578-6	Flammable Liquid – Category 3 – H225	25% - 35%
Synthetic Resin	Proprietary	Proprietary	Skin Irritant – Category 2 – H315	<60%

See Section 16 for Hazard and Precautionary Statement Key.

**Section 4 – First Aid Measures**

Routes of Exposure	First Aid Instructions
Eye	Immediately flush with water for 15 minutes, holding the eyelids apart. Get medical help if discomfort persists.
Skin	Wash thoroughly with soap and water. Remove contaminated clothing. Get medical help if discomfort persists.
Ingestion	If greater than normal dose is swallowed, do not induce vomiting. Drink large quantity of water, milk or milk of magnesia. Contact Poison Control.
Inhalation	None needed under normal use conditions. If irritation develops, move to fresh air. Get medical attention if symptoms persist.

**Section 5 – Fire Fighting Measures**

Extinguishing Media:	Carbon dioxide, dry chemical foam, alcohol-resistant foam. Do not use water.
Fire Fighting Instructions:	During a fire, irritating or highly toxic gases may be generated by thermal decomposition. If potential for exposure, wear complete personal protective equipment including self contained breathing apparatus, with full face operated in pressure demand.
Unusual Hazards:	Evacuate all personnel.

**Section 6 – Accidental Release Measures**

Personal Precautions, Protective Equipment and Emergency Procedures:	Remove people from danger area. Keep away from ignition sources. Wear protective clothing, eye protection, gloves and respiratory protective device. Avoid contact with eyes and skin.
Environmental Precautions:	Do not allow product to reach sewage system or any water course. Do not allow to penetrate the ground. Report releases as required by local and national authorities.
Methods and Materials for Containment and Clean-up:	Ensure adequate ventilation. Collect using an inert non-combustible absorbent material and place in appropriate containers for disposal.

**Section 7 – Handling and Storage**

Precautions for Safe Handling:	Ensure good ventilation/exhaustion at the workplace. Avoid contact with the eyes and skin. Avoid breathing vapors. Keep product away from heat, sparks, flames and other sources of ignition. Use in accordance with package instructions.
Conditions for Safe Storage:	Store in a cool, well ventilated area away from oxidizing agents and direct sunlight. Avoid excessive heat and ignition sources. Do not store together with acids.

**Section 8 – Exposure Controls / Personal Protection**

**Occupational Exposure Limits:**



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Sodium Fluoride	United States – 0.5mg/m3 ACGIH TLV TWA, 2.5mg/m3 US OSHA PEL TWA Germany – 2.5mg/m3 TWA EU IOEL United Kingdom – 2.5mg/m3 TWA UK OEL France – 2mg/m3 INRS VME Spain – 2.5mg/m3 VLA-ED Italy – 2.5mg/m3 8 hr. Value Limit European Union – 2.5mg/m3 TWA EU IOEL
Ethanol	United States – 1000 ppm TWA OSHA PEL, 1000 ppm TWA ACGIH TLV STEL Germany – 500 ppm TWA DFG MAK United Kingdom – 1000 ppm TWA UK OEL France – 1000 ppm TWA INRS VME, 5000 ppm VLCT Spain – 1000 ppm TWA VLA-ED Italy – None Established European Union – None Established
Synthetic Resin	United States – None Established Germany – None Established United Kingdom – None Established France – None Established Spain – None Established Italy – None Established European Union – None Established
Engineering Controls	Use with adequate general and local ventilation to minimize exposure levels.

### Personal Protective Equipment:

General Measures:	To identify additional Personal Protective Equipment (PPE) requirements, it is recommended that a hazard assessment in accordance with the OSHA PPE Standard (29CFR1910.132), or European Standard EN166 be conducted before using this product.
Eye/ Face Protection:	Safety glasses / goggles or splash shields are required when handling. Ensure eye bath is on hand.
Skin Protection:	Use impermeable clothing to prevent ANY contact with this product, such as gloves, apron, boots, or whole body suit.
Respiratory Protection:	In case of insufficient ventilation, wear suitable respiratory equipment.
Thermal Hazards:	Not Applicable

### Section 9 – Physical and Chemical Properties

Appearance	Odor & Odor Threshold	pH	Relative Density	Viscosity	% Volatile		
Off-White Viscous Liquid	Product Specific	6.6	1.1 g/ml	<6000cps	N/A		
Boiling Point/ Freezing Point (°F/°C)	Decomposition Temperature	Octanol/Water Partitioning Coefficient Log Po/w	Vapor Pressure:	Vapor Density	Evaporation Rate	Ignition	Solubility In Water (20°C)
170/79	N/DA	N/DA	N/DA	N/DA	N/DA	N/A	N/A
Flash Point (°F/°C)	Flammable Limit (vol%)	Auto-ignition Temperature (vol%)		Explosion Limits			



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56/14	N/A	N/A	LEL: 3.5 UEL: 15.0
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### Section 10 – Stability and Reactivity

<b>Chemical Stability:</b> Stable at ambient temperature	<b>Incompatible Materials:</b> Avoid oxidizing agents
<b>Possibility of Hazardous Reactions:</b> None known	<b>Hazardous Decomposition Products:</b> None Known
<b>Conditions to Avoid:</b> Keep away from heat, sparks and all ignition sources.	

### Section 11 – Toxicological Information

**Acute Toxicity:**

LD/LC50 values that are relevant for classification: No further relevant information available.

**Primary irritant effect:**

on the skin: Irritant to skin and mucous membranes.

on the eye: Irritating effect.

**Sensitization:** No sensitizing effects known.

**Experience with humans:**

May cause damage to central nervous system.

May cause damage to liver.

May cause damage to lungs.

**Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

Harmful

Irritant

**Carcinogenic categories:**

IARC (International Agency for Research on Cancer)	
Ethanol	1
Sodium Fluoride	3
Synthetic Resin	3

**NTP (National Toxicology Program)**

None of the ingredients is listed.

**OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

**Carcinogenic categories’ legend:**

IARC Group 1: The agent is carcinogenic to humans.

IARC Group 2A: The agent is probably carcinogenic to humans.

IARC Group 2B: The agent is possibly carcinogenic to humans.

IARC Group 3: The agent is not classifiable as to its carcinogenicity to humans.

IARC Group 4: The agent is probably not carcinogenic to humans.

NTP K: Known to be human carcinogen.

NTP R: Reasonably anticipated to be human carcinogen.

**Additional carcinogenic information:**

The substance ethanol is listed by IARC as a Group 1 carcinogen but in alcoholic beverage consumption. IARC Volume 100E (2012) “Personal Habits and Indoor Combustions” stated in its monograph “Consumption of Alcoholic Beverages” the following evaluation: “Ethanol in alcoholic beverages is carcinogenic to humans (Group 1).”

**Section 12 – Ecological Information**

<b>Toxicity:</b>	Sodium Fluoride: 96hr LC50 Oncorhynchus mykiss (Rainbow trout) 83.7 mg/L, 48hr EC50 daphnia magna 98 mg/L. Ethanol: 96hr LC50 fathead minnow 4,200 mg/L, 48hr EC50 daphnia magna Synthetic Resin: 48hr EC50 daphnia magna > 1.5mg/L
<b>Persistence and Degradability:</b>	Biodegradation is not applicable to inorganic substances such as sodium fluoride. Ethanol: Readily biodegradable (84% after 20 days). Synthetic Resin: has been shown to degrade > 25% in 28 days.
<b>Bio-accumulative Potential:</b>	No data is available.
<b>Mobility in Soil:</b>	Ethanol has a high mobility in soil.
<b>Other Adverse Effects:</b>	No data available.
<b>Results of PBT/vPvB Assessment:</b>	No data available.

**Section 13 – Disposal Considerations**

<b>Regulations:</b>	Dispose in accordance with local and national environmental regulations.
<b>Properties (Physical/Chemical) Affecting Disposal:</b>	None known.
<b>Waste Treatment Recommendations:</b>	None needed for normal anticipated use.

**Section 14 – Transport Information**

<b>UN Number: UN1170</b>				
<b>UN proper shipping name:</b> ADR/RID: Ethanol IMDG: Ethanol IATA: Ethanol DOT: Ethanol				
UN Number:	ADR/RID:	IMDG:	IATA:	DOT:
<b>Transport hazard class(es):</b>	3	3	3	3
<b>Packaging group:</b>	II	II	II	II
<b>Environmental hazards:</b>	No	Marine Pollutant: No	No	No
<b>Special precautions for user:</b>	Not Applicable			

**Section 15 – Regulatory Information**

**US Federal Regulations**

Clean Air Act: HAP/ODS	This product contains the following HAP’s or ODS: • None
Clean Water Act: Priority Pollutant	This product contains the following chemicals listed under the U. S. Clean Water Act Priority Pollutant and Hazardous Substance List: • None
FDA: Food Packaging Status	This product has not been cleared by the FDA for use in food packaging and /or other applications as an indirect food-packaging additive.
Occupational Safety and Health Act	This product is not considered to be hazardous under the OSHA Hazard Communication Standard.



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RCRA	This product contains the following chemicals considered to be hazardous waste under RCRA ( 40 CFR 261). <ul style="list-style-type: none"> <li>None</li> </ul>
SARA Title III: Section 302 (RQ)	This product contains no chemicals regulated under Section 302 as extremely hazardous substances.
SARA Title III: Section 302 (TPQ)	This product contains chemicals regulated under Section 304 as extremely hazardous chemicals for emergency release notification (“CERCLA” List): <ul style="list-style-type: none"> <li>Sodium Fluoride – CAS #7681-49-4 1000 # RQ</li> </ul>
SARA Title III: Section 311-312:	This product is considered to be hazardous under the OSHA Hazard Communication Standard and is regulated under Section 311-312 (40 CFR 370). It’s hazards are: <ul style="list-style-type: none"> <li>Sodium Fluoride – CAS# 7681-49-4 (Corrosive)</li> </ul>
SARA Title III: Section 313:	This product contains the following chemicals which are subject to the reporting requirements of Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372: <ul style="list-style-type: none"> <li>None</li> </ul>
TSCA Section 8(b): Inventory: TSCA Significant New Use Rule:	This product does contain chemicals listed on the TSCA inventory or otherwise complies with TSCA pre-manufacture notification requirements. <ul style="list-style-type: none"> <li>Sodium Fluoride – CAS# 7681-49-4</li> </ul> None of the chemicals in this material have a SNUR under TSCA.

### State Regulations:

**California:** This product does not contain chemicals known to the State of California to cause cancer, birth defects or reproductive harm.

### International Regulations

CDSL: Canadian Inventory (on Canadian Transitional List)	Sodium Fluoride – CAS# 7681-49-4
EU REACH: This product is a medicinal product and not subject to registration requirements.	

## Section 16 – Other Information

Abbreviations and acronyms:	
<b>GHS:</b>	Globally Harmonized System of Classification and Labeling of Chemicals
<b>HCS:</b>	Hazard Communication Standard (USA)
<b>SDS:</b>	Safety Data Sheet
<b>ECHA:</b>	European Chemicals Agency
<b>OSHA:</b>	Occupational Safety and Health Administration
<b>ADR:</b>	European Agreement concerning the International Carriage of Dangerous Goods by Road
<b>IMDG:</b>	International Maritime Code for Dangerous Goods
<b>DOT:</b>	US Department of Transportation
<b>IATA:</b>	International Air Transport Association
<b>ACGIH:</b>	American Conference of Governmental Industrial Hygienists
<b>CAS:</b>	Chemical Abstracts Service (division of the American Chemical Society)
<b>NFPA:</b>	National Fire Protection Association
<b>HMIS:</b>	Hazardous Materials Identification System
<b>VOC:</b>	Volatile Organic Compounds
<b>LC50:</b>	Lethal Concentration, 50%
<b>LD50:</b>	Lethal Dose, 50%



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<b>PBT:</b>	Persistent, Bioaccumulative and Toxic
<b>vPvB:</b>	very Persistent and very Bioaccumulative
<b>Xi:</b>	Irritant
<b>T:</b>	Toxic
<b>F:</b>	Highly Flammable

<b>Date Sources:</b>
<b>OSHA</b> – <a href="http://www.osha.gov/dts/chemicalssampling/toc/chmcas.html">www.osha.gov/dts/chemicalssampling/toc/chmcas.html</a>
<b>TOXNET</b> – <a href="http://www.toxnet.nlm.nih.gov">www.toxnet.nlm.nih.gov</a>
<b>ECHA</b> – <a href="http://www.echa.europa.eu">www.echa.europa.eu</a>
<b>EnviChem</b> – <a href="http://www.echemportal.org">www.echemportal.org</a>

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