



practitioner series™

# S A F E T Y   D A T A   S H E E T

## SECTION I: Identification

### Product Identifier:

**Product Name:** Oral-B® 5% Sodium Fluoride Varnish

**Part/Item Number:** 295097, 295098, 295099, 295100, 295101, 295102, 295103, 295104, 295105

### Recommended Use of the Substance or Mixture and Restrictions on Use:

**Recommended Use:** Dental Product

**Restrictions on Use:** For use by dental professional only

### Details of the Supplier:

**Manufactured for:** Young Dental Manufacturing  
13705 Shoreline Court East  
Earth City, MO 63045  
1.800.325.1881

### Emergency Phone Number:

**Infotrac:**

**24-Hour Number-** (U.S.) 1-800-535-5053

**Outside U.S.-** 1-352-323-3500

## SECTION II: Hazard(s) Identification

### Classification of the Substance or Mixture:

Health Hazard	Physical Hazard
Acute Toxicity Category 3	Flammable Liquid Category 2
Eye Irritant Category 2	
Skin Sensitizer Category 1	

### Label Elements:

#### Hazard Symbol:



**Signal Word:** Danger

#### **Hazard Statement(s):**

Highly flammable liquid and vapor

Harmful if swallowed

Causes serious eye irritation

**Precautionary Statement(s):**

Keep away from heat, sparks, open flames, and hot surfaces. No smoking.  
Keep out of the reach of children.  
Wash hands thoroughly after handling.

**Other Hazards:** None

**Unknown Acute Toxicity:** No ingredient with unknown toxicity.

**SECTION III: Composition/Information on Ingredients**

Component	CAS #/EINECS No.	WT%
Ethanol	64-17-5/200-578-6	20-35%
Sodium Fluoride	7681-49-4/231-667-8	4-6%
Rosin, hydrogenated	65997-06-0/266-041-3	50-70%

**SECTION IV: First-Aid Measures****Description of First Aid Measures:**

**Eye contact** – Flush eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention if irritation develops or persists.

**Skin contact** – Wash skin with plenty of soap and water. Get medical attention if irritation develops.

**Ingestion** – Do not induce vomiting. If conscious, rinse out mouth with water and give copious amounts of milk, or water if milk is not available. Never give anything by mouth to an unconscious person. If symptoms persist, get immediate medical attention.

**Inhalation** – Move victim to fresh air. If breathing is difficult, have qualified personnel administer oxygen. Get medical attention if irritation persists.

**Most Important Symptoms and Effects, Acute and Delayed:** May cause eye and skin irritation. May cause skin sensitization. May be harmful if swallowed.

**Indication of Any Immediate Medical Attention and Special Treatment Needed:** No information available

**SECTION V: Firefighting Measures**

**Extinguishing media:** Use media appropriate for surrounding fire.

**Special Hazards Arising from the Substance or Mixture:** Highly flammable liquid and vapor

**Advice for Fire-Fighters:**

**Special Protective Equipment and Precautions for Firefighters** - Firefighters should wear full emergency equipment and positive pressure self-contained breathing apparatus.

**Unusual Fire/Explosion Hazards** – None under normal conditions of use.

**Known or Anticipated Hazardous Products of Combustion** – Carbon monoxide, carbon dioxide, and toxic fumes.

**SECTION VI: Accidental Release Measures**

**Personal Precautions, Protective Equipment, and Emergency Procedures:** Avoid contact with eyes, skin, and clothing. Use appropriate protective equipment as described in Section 8.

**Environmental Precautions:** Prevent spill from entering waterways.

**Methods and Materials for Containment and Cleaning Up:** Wipe up or collect using an inert absorbent material and place in appropriate containers for disposal. Rinse spill area with water. Prevent spill from entering sewers and water

courses. Report releases as required by local, state, and federal authorities.

## **SECTION VII: Handling and Storage**

**Precautions for Safe Handling:** Avoid contact with the eyes, skin and clothing. Wear protective clothing and equipment as described in Section 8. Wash thoroughly with soap and water after handling. Keep containers tightly closed when not in use. Do not reuse containers. Empty containers retain product residues that can be hazardous. Follow all safety precautions when handling empty containers.

**Conditions for Safe Storage, Including Any Incompatibilities:** Store in a cool, dry, well-ventilated area. Do not store above 25°C (77°F). Keep out of direct sunlight. Keep away from heat and ignition sources. Keep out of reach of children.

## **SECTION VIII: Exposure Controls/Personal Protection**

**Control Parameters:** The parameters are not provided for the product itself. They are provided for the ingredients listed below.

<b>Occupational Exposure Limits:</b>		
<b>Component</b>	<b>TWA OSHA</b>	<b>ACGIH</b>
Sodium Fluoride (as fluoride)	2.5 mg/m <sup>3</sup>	2.5 mg/m <sup>3</sup> TWA ACGIH
Ethanol	1900 mg/m <sup>3</sup>	1000 ppm STEL ACGIH

### **Exposure Controls:**

**Appropriate Engineering Controls** - No special ventilation normally required. For bulk handling, use ventilation that is adequate to maintain exposure levels below the occupational exposure limits.

**Individual Protection Measures (PPE) - Eye Protection:** Safety glasses recommended.

**Respiratory Protection:** None should be needed for normal use. If the exposure limits are exceeded an approved respirator with particulate cartridges or air respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice. **Other Protective Clothing or Equipment:** None needed for normal use. Impervious clothing as needed to avoid contamination of personal clothing for bulk handling.

## **SECTION IX: Physical and Chemical Properties**

<b>Information on Physical and Chemical Properties:</b>	
<b>Appearance:</b>	Off white to white colored liquid
<b>Odor:</b>	Characteristic
<b>Odor Threshold:</b>	Not available
<b>pH:</b>	Not applicable
<b>Melting point/freezing point:</b>	Not applicable/Not available
<b>Initial boiling point and boiling range:</b>	Not available
<b>Flash point:</b>	Not available
<b>Evaporation rate (Butyl Acetate =1):</b>	Not available
<b>Flammability (solid, gas):</b>	Not available
<b>Upper/lower flammability or exposure limits:</b>	LEL: Not available UEL: Not available
<b>Vapor pressure:</b>	Not available
<b>Vapor density (Air = 1):</b>	Not available
<b>Relative density:</b>	Not available

<b>Solubilit(ies):</b>	Slightly soluble
<b>Partition coefficient: n-octano/water</b>	Not available
<b>Auto-ignition temperature:</b>	Not available
<b>Decomposition temperature:</b>	Not available
<b>Viscosity:</b>	Not available

## **SECTION X: Stability and Reactivity**

**Reactivity:** None known

**Chemical Stability:** Stable

**Possibility of hazardous reactions:** None under normal conditions of use.

**Conditions to avoid:** Keep away from ignition sources, heat.

**Incompatible materials:** Avoid oxidizing agents and strong acids.

**Hazardous decomposition products:** May produce carbon monoxide, carbon dioxide and toxic fumes.

## **SECTION XI: Toxicological Information**

Toxicological data are not available for the product itself. The data provided are for the ingredients listed below.

### **Potential Health Effects:**

**Ingestion** - May cause salivation, nausea, vomiting, abdominal pain, headaches, or dizziness.

**Eye Contact** – Direct contact causes eye irritation

**Skin Contact** – Prolonged skin contact may cause irritation.

**Inhalation** - No adverse effects expected, under normal conditions of use.

**Chronic Health Effects:** Not expected under normal conditions of use. Repeated overexposure to Sodium Fluoride may cause fluorosis.

### **Acute Toxicity Data:**

**Sodium Fluoride** – Oral rat LD50: 52mg/kg

**Ethanol** - Oral rat LD50: 7060 mg/kg

**Medical Conditions Aggravated by Exposure:** Individuals with pre-existing skin disease may be at increased risk from exposure. May cause skin sensitization in susceptible individuals.

**Carcinogenicity:** Not known to be as carcinogen or potential carcinogen by NTP (National Toxicological Program), IARC (International Agency for the Research of Cancer) or OSHA (Occupational Safety and Health Administration).

**Mutagenicity:** No data available

## **SECTION XII: Ecological Information**

Ecological data not available for the product itself. The data provided are for the ingredients listed below

### **Toxicity:**

**Sodium Fluoride** – 96 hrs. LC50 rainbow trout: 200 mg/L

**Ethanol** - 96 hrs. LC50 rainbow trout: >10,000 mg/L

**Persistence and Degradability:** No information available

**Bio-accumulative potential:** No data available

**Mobility in Soil:** No data available

**Other Adverse Effects:** No information available

## **SECTION XIII: Disposal Considerations**

Dispose of in accordance with all Federal, State and Local regulations.

## **SECTION XIV: Transport Information**

### **DOT:**

**Proper Shipping Name** – Ethanol solution

**Hazard Class** – 3

**UN Number** – UN 1170

**Packing Group** – II

**Packaging** - See 49 CFR 173.202 for authorized specification non-bulk packagings.

**Limited Quantity and Consumer Commodity Exception** - See 49 CFR 173.150 for limited quantity and consumer commodity exceptions (valid until 12/31/2020). Inner packagings which do not exceed 1 L and outer packagings not exceeding 30 kg are authorized.

**Hazardous Substances (RQ)** – Ethanol is not listed as a hazardous substance.

### **IATA/ICAO:**

**Proper Shipping Name** – Ethanol solution

**Hazard Class** - 3

**UN Number** – UN 1170

**Packing Group** – II

**Limited Quantity Exception** – See Packing Instruction Y341. Up to 0.5 L maximum quantity per inner package (depending on type of package used) and 1 L / 30 kg gross weight maximum per package. Combination packages are required.

**Consumer Commodity Exception** - See Packing Instruction Y963. If inner packages are not more than 500 mL and material is packaged for consumer use, it may be reclassified as ID8000, Consumer Commodity, Class 9. Gross weight is 30 kg.

**Passenger Aircraft Limitation** - See Packing Instruction 353. Up to 5 L maximum quantity per inner package (depending on inner package used) and 5 L maximum net quantity per package. Combination and single packages are permitted.

**Cargo Aircraft Limitation** - See Packing Instruction 364. Up to 10 L maximum quantity per inner package (depending on inner package used) and 60 L maximum net quantity per package. Combination and single packages are permitted.

### **IMDG/IMO:**

**Proper Shipping Name** – Ethanol solution

**Hazard Class** – 3

**UN Number** – UN 1170

**Packing Group** – II

## **SECTION XV: Regulatory Information**

### **US Federal Regulations:**

#### **SARA TITLE III:**

**Hazard Category for Section 311/312** – Acute Health, Fire Hazard

**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 at or above reportable quantity.

**Section 302 extremely hazardous Substances (TPQ)** - None at or above reportable quantity

**EPA Toxic Substances Control Act (TSCA) Status** - This product is not subject to chemical notification requirements.

Note: The regulatory information given above only indicates the principal regulations specifically applicable to the product described in the safety data sheet. The user's attention is drawn to the possible existence of additional provisions which complete these regulations. Refer to all applicable national, international and local regulations or provisions.

## **SECTION XVI: Other Information**

**Risk phrases used in Section 2:** Not applicable

**Supersedes:** 21 January 2015

**Date Revised:** 18 May 2015

---

The information contained herein is provided in good faith and is believed to be correct as of the date hereof. However, Young Dental Manufacturing makes no recommendation as to the comprehensiveness or accuracy of the information. It is expected that individuals receiving the information will exercise their independent judgment in determining its appropriateness for particular purpose.

NO REPRESENTATIONS, OR WARRANTIES, EITHER EXPRESSED OR IMPLIED OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER NATURE ARE MADE HEREUNDER WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR TO THE PRODUCT TO WHICH THE INFORMATION REFERS.

---