



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.

Occupational Exposure Limits:		
Component	TWA OSHA	ACGIH
Sodium Fluoride (as fluoride)	2.5 mg/m ³	2.5 mg/m ³ TWA ACGIH
Ethanol	1900 mg/m ³	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

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

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

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