

SECTION 1: IDENTIFICATION

Product Identifier

Varnish Sodium Fluoride 5%

Other Means of Identification

AMD Medicom Item Code(s): List of Products in Annex

Company AddressAMD Medicom Inc.
2555 Chemin de l'Aviation
Pointe-Claire, Montréal, Québec, H9P 2Z2**Telephone Number (Canada):** 514-636-6262**Emergency Telephone Number:** 1-800-361-2862

SECTION 2: HAZARD IDENTIFICATION

GHS Classification : Flammable liquid category 2
Acute Toxicity category 3
Eye Irritant category 2
Skin Sensitizer category 1**Signal Word:** Danger**Hazard Statements:** Highly flammable liquid and vapor
Harmful if swallowed
Causes serious eye irritation**Pictogram:****Flammable Harmful
Irritant****Precautionary Statements:** Keep away from heat. Sparks, open flames, and hot surfaces. No smoking.
Keep out of the reach of children.
Wash hands thoroughly after handling.**Hazards not otherwise classified:** None**Unknown Acute Toxicity:** No ingredient with unknown toxicity

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Percent (By Weight)	CAS No.	EINECS No.
Ethanol	10-35%	64-17-5	200-578-6
Sodium Fluoride	4-5%	7681-49-4	231-667-8
Synthetic Resin	50-70%	68990-02-3	273-574-5

SECTION 4: 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.
Advice to Physician:	No specific advice

SECTION 5: FIRE FIGHTING MEASURES

Extinguisher to Use:	Use media appropriate for the surrounding fire.
Specific hazards:	Highly flammable liquid and vapor.
Unusual Fire/ Explosion Hazards:	None under normal conditions of use.
Products of Combustion:	Carbon monoxide, carbon dioxide, and toxic fumes
Fire Fighting Procedures and Personal Protection:	Wear full emergency equipment and positive pressure self-contained breathing apparatus.

SECTION 6: 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 7: HANDLING AND STORAGE

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.
Storage:	Store between 15-30°C (59°F-86°F). Keep out of direct sunlight. Keep away from heat and ignition sources. Keep out of reach of children. Store away from strong acids and oxidizing materials.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure controls: The parameters are not provided for the product itself. They are provided for the ingredients listed below:

Sodium Fluoride (as Fluoride)	2.5mg/m³ TWA ACGIH 2.5mg/ m³ TWA OSHA
Ethanol	1000 ppm STEL ACGIH 1900 mg/m³ TWA OSHA

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.

Personal Protective Equipment
Eye Protection: Safety glasses recommended.

Skin Protection: Wear impervious gloves.

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: None needed for normal use. Impervious clothing as needed to avoid contamination of personal clothing for bulk handling.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Color/ Appearance	Off-white to yellow-colored liquid
Odor	Characteristic
Odor Threshold	N/A
pH	N/A
Boiling point/Range	N/A
Melting point	N/A
Freezing point	N/A
Flashpoint	N/A
Evaporation Rate	N/A
Flammability (solid, gas)	N/A
Upper/lower flammability or explosive limits	N/A
Vapor Pressure	N/A
Vapor Density	N/A
Relative Density	N/A
Solubility in Water	Slightly soluble
Partition coefficient (n-octanol/water)	N/A
Autoignition Temperature	N/A
Decomposition Temperature	N/A
Viscosity	N/A

SECTION 10: 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.

Hazardous Decomposition Products: May produce carbon monoxide, carbon dioxide, and toxic fumes.

Incompatibility Materials: Avoid oxidizing agents and strong acids.

SECTION 11: TOXICOLOGICAL INFORMATION
Information on Toxicological Effects: Toxicological data not available for the product itself. The data provided are for the ingredients listed below:

Sodium Fluoride	Oral rat LD ₅₀ : 52 mg/kg
Ethanol	Oral rat LD ₅₀ : 7060 mg/kg

Likely Routes of Exposure and the Symptoms related to the Physical, Chemical, and Toxicological Characteristics

Eyes:	Direct contact causes eye irritation.
Skin:	Prolonged skin contact may cause irritation.
Inhalation:	No adverse effects expected, under normal conditions of use.
Ingestion:	May cause salivation, nausea, vomiting, abdominal pain, headaches, or dizziness.
Chronic Health Effects:	Not expected under normal conditions of use. Repeated overexposure to Sodium Fluoride may cause fluorosis.
Mutagenicity:	N/A
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). Carcinogenicity of ethanol is only applicable when it is present in alcoholic beverages only.

Medical Conditions Aggravated by Exposure: Individuals with pre-existing skin and respiratory disease may be at increased risk from exposure.

SECTION 12: ECOLOGICAL INFORMATION

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

Sodium Fluoride	96 hrs. LC ₅₀ rainbow trout: 51-108 mg/L
Ethanol	96 hrs. LC ₅₀ rainbow trout: > 10,000 mg/L

Persistence and degradability:	N/A
Bioaccumulation Potential:	N/A
Mobility in soil:	N/A
Other adverse effects:	N/A

SECTION 13: DISPOSAL CONSIDERATIONS

Consult current local, state, and federal regulations for proper disposal methods

SECTION 14: TRANSPORT AND STORAGE

*Please refer to local, state, and national transport regulations as limited quantity exceptions may apply for the product as supplied, before the use of the information provided in this section.

DOT:

Proper Shipping Name – Ethanol solution

Hazard Class – 3

UN Number – UN 1170

Packing Group – III

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 – III

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 – III

SECTION 15: REGULATORY INFORMATION

U.S. 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 a medical device and 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 16: OTHER INFORMATION

Legal disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. AMD Medicom Inc. shall not be held liable for any damage resulting from handling or from contact with the products listed in Annex.

ANNEX: LIST OF PRODUCTS

Item Code No.	Description
1030-MM32	Medicom Duraflor Halo 5% Sodium Fluoride White Varnish, 0.5ml/tray, Melon Mint flavor
1030-SM250	Medicom Duraflor Halo 5% Sodium Fluoride White Varnish, 0.5ml/tray, Spearmint flavor
1030-SM32	Medicom Duraflor Halo 5% Sodium Fluoride White Varnish, 0.5ml/tray, Spearmint flavor
1030-WB250	Medicom Duraflor Halo 5% Sodium Fluoride White Varnish, 0.5ml/tray, Wild Berry flavor
1030-WB32	Medicom Duraflor Halo 5% Sodium Fluoride White Varnish, 0.5ml/tray, Wild Berry flavor
SP-1030	SAMPLE - Medicom Duraflor Halo 5% Sodium Fluoride White Varnish, 0.5ml/tray