

1. IDENTIFICATION

Product Trade Name	ipana 5% Sodium Fluoride Varnish (NPN 80034153) Item 40530 – Caramel Item 40531 – Wintergreen Mint Item 40532 – Bubble Gum Item 40533 - Melon
Manufacturer	maxill inc.
Address	80 Elm Street St. Thomas, ON N5R 6C8
Telephone	+1 519-631-7370, FAX +1 519-631-3388
Website	www.maxill.com
Emergency telephone	maxill 1-800-268-8633
Emergency telephone (24h)	CANUTEC 1-888-226-8832 (1-888-CAN-UTEC) ChemTel 1-800-255-3924, +1-813-248-0585
Supplier	See above.

2. HAZARDS IDENTIFICATION

Physical hazards	Not classified	
Health hazards	Flammable liquids	Category 4
	Acute toxicity – oral	Category 4
	Skin corrosion/irritation	Category 2
	Eye damage/irritation	Category 2
	Sensitization - respiratory	Category 1
	Sensitization – skin	Category 1
Environmental hazards	Not classified	
WHMIS 2015 defined hazards	Not available	
Label elements		



Hazard symbol
Signal word
Hazard statement

Danger
 Combustible liquid
 Harmful if swallowed
 Causes skin irritation
 Causes serious eye irritation
 May cause allergy or asthma symptoms or breathing difficulties if inhaled
 May cause an allergic skin reaction

Precautionary statement

Prevention

Keep away from heat, hot surfaces, spark, open flames and other ignition sources. No smoking.
 Wear protective gloves, eye protection.
 Wash hands thoroughly after handling with soap and water.
 Do not eat, drink or smoke when using this product.
 Avoid breathing mist or spray.
 Contaminated work clothing should not be allowed out of the workplace.

Response

In case of fire: Use appropriate media to extinguish.
 IF SWALLOWED: Get medical help. Rinse mouth if spilled in mouth.
 IF ON SKIN: Wash with plenty of soap and water. Specific treatment (see section 4 of the SDS). If skin irritation or rash occurs: Get medical help. Take off contaminated clothing and wash it before reuse.
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical help.
 IF INHALED: (For allergic reaction), remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Get emergency medical help immediately.

Storage

Store in a well-ventilated place

Disposal

Dispose of waste and residues in accordance with local, regional, national and international regulations.

WHMIS 2015: Health Hazard(s) not otherwise classified (HHNOC)

None known

WHMIS 2015: Physical Hazard(s) not otherwise classified (PHNOC)

None known

Hazard(s) not otherwise classified (HNOC)

None known

Supplemental information

Exempt – Natural Health Product

This product is not subject to the Hazardous Products Act (HPA) Part II (Hazardous Products) as per paragraph 12(j); Schedule 1 (Non-Application of Part II).

This restriction states that Part II does not apply in respect of the sale or importation of anything listed in Schedule 1 which includes any pest control product as defined in subsection 2(1) of the Pest Control Products Act, any explosive as defined in section 2 of the Explosives Act, any cosmetic, device, drug or food, as defined in section 2 of the Food and Drugs Act, any consumer product as defined in section 2 of the Canada Consumer Product Safety Act and any wood or product made of wood.

3. Composition / Information on ingredients

Mixture

Ingredient	CAS #	% by wt.
Rosin	8050-09-7	45 – 70%
Ethanol	64-17-5	10 – 30%
Sodium fluoride	7681-49-4	3 – 7%

GHS Classifications

Rosin: Skin corrosion/irritation (Cat 2), Eye damage/ irritation (Cat 2), Sensitization – respiratory (Cat 1), Sensitization – skin (Cat 1)

Ethanol: Flammable liquids (Cat 2), Skin corrosion/irritation (Cat 2), Eye damage/irritation (Cat 2)

Sodium Fluoride: Acute toxicity – oral (Cat 4), Skin corrosion/irritation (Cat 2), Eye damage/irritation (Cat 2)

Composition comments US GHS: The exact percentage (concentration) of composition has been withheld as a trade secret in accordance with paragraph (i) of §1910.1200.

CANADA GHS: The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation	No harm anticipated from materials in quantities as packaged. Monitor patient for allergic reaction to rosin (colophony). Get medical help.
Skin contact	There may be mild irritation at the site of contact. Wash promptly with soap and water.
Eyes contact	If contact occurs, rinse thoroughly with water. Irritation or redness may occur.
Ingestion	If a spill occurs in the mouth, rinse mouth. There may be irritation of the mouth or throat. Monitor patient for allergic reaction to rosin (colophony). Get medical help.

5. Fire-fighting measures

Suitable extinguishing media	For fire: water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Not available.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire-fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.
Hazardous combustion products	May include and are not limited to oxides of carbon

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Neutralize spills with mild alkalines. Clean the surface thoroughly to remove residual contamination. For disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground. Do not discharge into lakes, streams, ponds or public waters.

7. Handling and storage

Precautions for safe handling	Observe good industrial hygiene practices. For use by dental professionals only. Unit dose packages are to used on one patient only and disposed.
Conditions for safe storage	Store in original tightly closed container, at room temperature. Exposure controls / personal protection

8. Exposure controls / personal protection

Exposure controls	PEL: Not established, TLV: Not established
Respiratory protection	Not required
Skin protection	Impervious gloves. Avoid contact with skin. Wash with soap and water.
Hand protection	Impervious gloves.

Eye protection

Safety eyewear.

9. Physical and chemical properties

Appearance	Soft, whitish paste which thins out to a transparent layer
Odour	Characteristic odour of applicable flavour
pH	Not determined
Boiling point	Not determined
Melting point	Not determined
Flash point	Not determined
Auto-Ignition Temperature	Not determined
Flammability	Not determined
Explosive Limits in Air	Not applicable
Oxidizing Properties	Not applicable
Vapor Pressure	Not determined
Vapor Density (Air=1)	Not determined
Specific Gravity (H₂O =1)	Not determined
Solubility in Water	Not available
Reactivity in Water	Not available

10. Stability and reactivity

Reactivity	May react with incompatible materials.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Chemical stability	Material is stable under normal conditions.
Conditions to avoid	Heat
Incompatible materials	Strong oxidizing agents, strong acids
Hazardous decomposition products	In combustion, emits toxic fumes

11. Toxicological information

Routes of exposure	See Section 4 for routes of exposure and corresponding symptoms
Information on likely routes of exposure	
Skin contact	Causes skin irritation
Eye contact	Causes serious eye irritation
Acute eye effects	Eye irritation
Acute dermal effects	Skin irritation
Acute inhalation effects	Not established
Acute oral effects	Chronic overdose of sodium fluoride may cause mottling of tooth enamel (Sodium Fluoride: Oral rat LD ₅₀ : 0.18g/kg)
Sensitization	This product has the potential to cause skin or respiratory sensitization.

Mutagenicity	Not available
Carcinogenicity	Not anticipated based on typical usage of this product
Reproductive toxicity	Not available
Teratogenicity	Not available
Aspiration hazard	Not an aspiration hazard
Other	Sodium fluoride varnishes have been used safely and effectively by dental professionals for more than 25 years.

12. Ecological information

Mobility	Readily absorbed into soil
Persistence and biodegradability	Biodegradable
Bioaccumulation potential	No bioaccumulation potential
Other	Follow government regulations; avoid release into environment Please refer to Section 6 for information regarding accidental releases and Section 15 for regulatory reporting information.

13. Disposal considerations

Disposal instructions (unused products, waste from residues, contaminated packaging)	Dispose of waste and residues in accordance with local, regional, national and international regulations.
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14. Transport information

Transport of Dangerous Goods (TDG – Canada)

Not regulated as dangerous goods.

Road/ Rail: 1.36 Class Flammable liquids, Alcoholic Beverage and Aqueous Solution of Alcohol
Exemption SOR/2008-34 (a)(i), Air: 12.1(2), ICAO TI A58

U.S. Department of Transportation (DOT)

Not regulated as dangerous goods. 49 CFR 173.150 (e) - Aqueous solutions of alcohol exemption

15. Regulatory information

Canadian federal regulations

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SAFETY DATA SHEET
ipana 5% Sodium Fluoride Varnish

product as defined in section 2 of the Canada Consumer Product Safety Act and any wood or product made of wood.
Exempt – registered product (NPN 80034153)

U.S. federal regulations

U.S. FDA Dental Device: Class 2

16. Other information

Product handling is exclusively by dental specialists per instructions for use.

Disclaimer

Information contained herein was obtained from sources considered technically accurate and reliable. While every effort has been made to ensure full disclosure of product hazards, in some cases data is not available and is so stated. Since conditions of actual product use are beyond control of the supplier, it is assumed that users of this material have been fully trained according to the requirements of all applicable legislation and regulatory instruments. No warranty, expressed or implied, is made and supplier will not be liable for any losses, injuries or consequential damages which may result from the use of or reliance on any information contained in this document.

For an updated SDS, please contact the supplier/manufacturer listed on the first page of the document.