

## 1. IDENTIFICATION

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

## 2. HAZARDS IDENTIFICATION

<b>Physical hazards</b>	Not classified	
<b>Health hazards</b>	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
<b>Environmental hazards</b>	Not classified	
<b>WHMIS 2015 defined hazards</b>	Not available	
<b>Label elements</b>		



<b>Hazard symbol</b>	
<b>Signal word</b>	Danger
<b>Hazard statement</b>	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**

<b>Ingredient</b>	<b>CAS #</b>	<b>% by wt.</b>
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

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

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

## 6. Accidental release measures

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

## 7. Handling and storage

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

## 8. Exposure controls / personal protection

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

**Eye protection**

Safety eyewear.

## 9. Physical and chemical properties

<b>Appearance</b>	Soft, whitish paste which thins out to a transparent layer
<b>Odour</b>	Characteristic odour of applicable flavour
<b>pH</b>	Not determined
<b>Boiling point</b>	Not determined
<b>Melting point</b>	Not determined
<b>Flash point</b>	Not determined
<b>Auto-Ignition Temperature</b>	Not determined
<b>Flammability</b>	Not determined
<b>Explosive Limits in Air</b>	Not applicable
<b>Oxidizing Properties</b>	Not applicable
<b>Vapor Pressure</b>	Not determined
<b>Vapor Density (Air=1)</b>	Not determined
<b>Specific Gravity (H<sub>2</sub>O =1)</b>	Not determined
<b>Solubility in Water</b>	Not available
<b>Reactivity in Water</b>	Not available

## 10. Stability and reactivity

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

## 11. Toxicological information

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

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

## 12. Ecological information

<b>Mobility</b>	Readily absorbed into soil
<b>Persistence and biodegradability</b>	Biodegradable
<b>Bioaccumulation potential</b>	No bioaccumulation potential
<b>Other</b>	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

<b>Disposal instructions (unused products, waste from residues, contaminated packaging)</b>	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.