

SAFETY DATA SHEETS

This SDS packet was issued with item:

070496497

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

070374819 070374835 070374876 071183201 071183219 071183227 071183276 071183284 071183292

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

070374884 070374892 070496430 070496448 070496455 070496489 070496513 071183367 071183375

Dentsply NUPRO 5% Sodium Fluoride White Varnish

Dentsply (Australia) Pty Ltd

Chemwatch Hazard Alert Code: 3

Chemwatch: 64-8045

Version No: 2.1.1.1

Safety Data Sheet according to WHS and ADG requirements

Issue Date: 28/07/2016

Print Date: 27/06/2017

S.GHS.AUS.EN

SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

Product Identifier

Product name	Dentsply NUPRO 5% Sodium Fluoride White Varnish
Synonyms	Product codes: 130210, 130211, 130212, 130213, 130214, 130215, 130218, 130219, 130220, 130221, 130222, 130223, 130224, 130226, 130227, 130210C, 130211C, 130212C, 130213C, 130214C, 130215C, 130218C, 130219C, 130220C, 130221C, 130222C, 130223C, 130224C, 130226C, 130227C
Proper shipping name	ISOPROPANOL (ISOPROPYL ALCOHOL)
Other means of identification	Not Available

Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	For Professional Use Only. One-step application that reduces dentinal hypersensitivity.
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Details of the supplier of the safety data sheet

Registered company name	Dentsply (Australia) Pty Ltd
Address	11-21 Gilby Road Mount Waverley VIC 3149 Australia
Telephone	1300 55 29 29
Fax	1300 55 31 31
Website	www.dentsply.com.au
Email	clientservices@dentsplysirona.com

Emergency telephone number

Association / Organisation	Not Available
Emergency telephone numbers	1300 55 29 29
Other emergency telephone numbers	Not Available

SECTION 2 HAZARDS IDENTIFICATION

Classification of the substance or mixture

HAZARDOUS CHEMICAL. DANGEROUS GOODS. According to the WHS Regulations and the ADG Code.

CHEMWATCH HAZARD RATINGS

	Min	Max
Flammability	3	4
Toxicity	2	3
Body Contact	2	3
Reactivity	2	3
Chronic	2	3

0 = Minimum
1 = Low
2 = Moderate
3 = High
4 = Extreme

Poisons Schedule	Not Applicable
Classification [1]	Flammable Liquid Category 2, Acute Toxicity (Oral) Category 4, Eye Irritation Category 2A, Skin Sensitizer Category 1, Specific target organ toxicity - single exposure Category 3 (narcotic effects)
Legend:	1. Classified by Chemwatch; 2. Classification drawn from HSIS; 3. Classification drawn from EC Directive 1272/2008 - Annex VI

Label elements

Hazard pictogram(s)	
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SIGNAL WORD	DANGER
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Hazard statement(s)

H225	Highly flammable liquid and vapour.
H302	Harmful if swallowed.

Continued...

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H319	Causes serious eye irritation.
H317	May cause an allergic skin reaction.
H336	May cause drowsiness or dizziness.
AUH032	Contact with acid liberates very toxic gas

Precautionary statement(s) Prevention

P210	Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P240	Ground/bond container and receiving equipment.

Precautionary statement(s) Response

P363	Wash contaminated clothing before reuse.
P370+P378	In case of fire: Use alcohol resistant foam or normal protein foam for extinction.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Precautionary statement(s) Storage

P403+P235	Store in a well-ventilated place. Keep cool.
P405	Store locked up.

Precautionary statement(s) Disposal

P501	Dispose of contents/container in accordance with local regulations.
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SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
72869-86-4	30-40	<u>diurethane dimethacrylate</u>
67-63-0	20-30	<u>isopropanol</u>
7681-49-4	4-6	<u>sodium fluoride</u>
13463-67-7	<1	<u>titanium dioxide</u>

SECTION 4 FIRST AID MEASURES

Description of first aid measures

Eye Contact	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> ▶ Wash out immediately with fresh running water. ▶ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. ▶ Seek medical attention without delay; if pain persists or recurs seek medical attention. ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	<p>If skin contact occurs:</p> <ul style="list-style-type: none"> ▶ Immediately remove all contaminated clothing, including footwear. ▶ Flush skin and hair with running water (and soap if available). ▶ Seek medical attention in event of irritation.
Inhalation	<ul style="list-style-type: none"> ▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▶ Other measures are usually unnecessary.
Ingestion	<ul style="list-style-type: none"> ▶ IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY. ▶ For advice, contact a Poisons Information Centre or a doctor. ▶ Urgent hospital treatment is likely to be needed. ▶ In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition. ▶ If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the SDS should be provided. Further action will be the responsibility of the medical specialist. ▶ If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the SDS. <p>Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:</p> <ul style="list-style-type: none"> ▶ INDUCE vomiting with fingers down the back of the throat, ONLY IF CONSCIOUS. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. <p>NOTE: Wear a protective glove when inducing vomiting by mechanical means.</p>

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 FIREFIGHTING MEASURES

Extinguishing media

- ▶ Alcohol stable foam.
- ▶ Dry chemical powder.
- ▶ BCF (where regulations permit).
- ▶ Carbon dioxide.

Special hazards arising from the substrate or mixture

Fire Incompatibility	▶ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
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Advice for firefighters

Fire Fighting	<ul style="list-style-type: none"> ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ May be violently or explosively reactive. ▶ Wear breathing apparatus plus protective gloves in the event of a fire. ▶ Prevent, by any means available, spillage from entering drains or water course.
Fire/Explosion Hazard	<ul style="list-style-type: none"> ▶ Liquid and vapour are highly flammable. ▶ Severe fire hazard when exposed to heat, flame and/or oxidisers. ▶ Vapour may travel a considerable distance to source of ignition. ▶ Heating may cause expansion or decomposition leading to violent rupture of containers. Combustion products include: <ul style="list-style-type: none"> · carbon dioxide (CO₂) · other pyrolysis products typical of burning organic material. May emit clouds of acrid smoke WARNING: Long standing in contact with air and light may result in the formation of potentially explosive peroxides.
HAZCHEM	•2YE

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	<ul style="list-style-type: none"> ▶ Remove all ignition sources. ▶ Clean up all spills immediately. ▶ Avoid breathing vapours and contact with skin and eyes. ▶ Control personal contact with the substance, by using protective equipment.
Major Spills	<ul style="list-style-type: none"> ▶ Clear area of personnel and move upwind. ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ May be violently or explosively reactive. ▶ Wear breathing apparatus plus protective gloves.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling

Safe handling	<ul style="list-style-type: none"> ▶ DO NOT allow clothing wet with material to stay in contact with skin ▶ Avoid all personal contact, including inhalation. ▶ Wear protective clothing when risk of exposure occurs. ▶ Use in a well-ventilated area. ▶ Prevent concentration in hollows and sumps.
Other information	<ul style="list-style-type: none"> ▶ Store below 38 deg. C. ▶ Store in original containers in approved flame-proof area. ▶ No smoking, naked lights, heat or ignition sources. ▶ DO NOT store in pits, depressions, basements or areas where vapours may be trapped. ▶ Keep containers securely sealed.

Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> ▶ Packing as supplied by manufacturer. ▶ Plastic containers may only be used if approved for flammable liquid. ▶ Check that containers are clearly labelled and free from leaks. ▶ For low viscosity materials (i) : Drums and jerry cans must be of the non-removable head type. (ii) : Where a can is to be used as an inner package, the can must have a screwed enclosure. ▶ For materials with a viscosity of at least 2680 cSt. (23 deg. C) ▶ For manufactured product having a viscosity of at least 250 cSt.
Storage incompatibility	<ul style="list-style-type: none"> ▶ Store below 38 deg. C. Alcohols <ul style="list-style-type: none"> ▶ are incompatible with strong acids, acid chlorides, acid anhydrides, oxidising and reducing agents.

Dentsply NUPRO 5% Sodium Fluoride White Varnish

- ▶ reacts, possibly violently, with alkaline metals and alkaline earth metals to produce hydrogen
- ▶ react with strong acids, strong caustics, aliphatic amines, isocyanates, acetaldehyde, benzoyl peroxide, chromic acid, chromium oxide, dialkylzincs, dichlorine oxide, ethylene oxide, hypochlorous acid, isopropyl chlorocarbonate, lithium tetrahydroaluminate, nitrogen dioxide, pentafluoroguanidine, phosphorus halides, phosphorus pentasulfide, tangerine oil, triethylaluminium, triisobutylaluminium
- ▶ should not be heated above 49 deg. C. when in contact with aluminium equipment
- ▶ Avoid reaction with oxidising agents

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA


Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Australia Exposure Standards	isopropanol	Isopropyl alcohol	983 mg/m ³ / 400 ppm	1230 mg/m ³ / 500 ppm	Not Available	Not Available
Australia Exposure Standards	titanium dioxide	Titanium dioxide	10 mg/m ³	Not Available	Not Available	Not Available

EMERGENCY LIMITS

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
diurethane dimethacrylate	Diurethane dimethacrylate	120 mg/m ³	1,300 mg/m ³	7,900 mg/m ³
isopropanol	Isopropyl alcohol	400 ppm	2000 ppm	12000 ppm
sodium fluoride	Sodium fluoride	17 mg/m ³	90 mg/m ³	1,100 mg/m ³
titanium dioxide	Titanium oxide; (Titanium dioxide)	30 mg/m ³	330 mg/m ³	2,000 mg/m ³

Ingredient	Original IDLH	Revised IDLH
diurethane dimethacrylate	Not Available	Not Available
isopropanol	12,000 ppm	2,000 [LEL] ppm
sodium fluoride	500 mg/m ³	250 mg/m ³
titanium dioxide	N.E. mg/m ³ / N.E. ppm	5,000 mg/m ³

Exposure controls

Appropriate engineering controls	<p>Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.</p> <p>The basic types of engineering controls are:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment.</p>
Personal protection	
Eye and face protection	<ul style="list-style-type: none"> ▶ Safety glasses with side shields. ▶ Chemical goggles. ▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task.
Skin protection	See Hand protection below
Hands/feet protection	<p>NOTE:</p> <ul style="list-style-type: none"> ▶ The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact. ▶ Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed. <p>The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.</p> <p>The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.</p> <p>Personal hygiene is a key element of effective hand care.</p>
Body protection	See Other protection below
Other protection	<ul style="list-style-type: none"> ▶ Overalls. ▶ PVC Apron. ▶ PVC protective suit may be required if exposure severe. ▶ Eyewash unit. • Some plastic personal protective equipment (PPE) (e.g. gloves, aprons, overshoes) are not recommended as they may produce static electricity. • For large scale or continuous use wear tight-weave non-static clothing (no metallic fasteners, cuffs or pockets). • Non sparking safety or conductive footwear should be considered. Conductive footwear describes a boot or shoe with a sole made from a conductive compound chemically bound to the bottom components, for permanent control to electrically ground the foot and shall dissipate static electricity from the body to reduce the possibility of ignition of volatile compounds.
Thermal hazards	Not Available

Recommended material(s)

GLOVE SELECTION INDEX

Glove selection is based on a modified presentation of the:

Respiratory protection

Type A Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

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"Forsberg Clothing Performance Index".

The effect(s) of the following substance(s) are taken into account in the **computer-generated** selection:

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Material	CPI
NAT+NEOPR+NITRILE	C
NATURAL RUBBER	C
NATURAL+NEOPRENE	C
NEOPRENE	C
NITRILE	C
NITRILE+PVC	C
PE/EVAL/PE	C
PVC	C
##sodium	fluoride

* CPI - Chemwatch Performance Index

A: Best Selection

B: Satisfactory; may degrade after 4 hours continuous immersion

C: Poor to Dangerous Choice for other than short term immersion

NOTE: As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -

* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

Where the concentration of gas/particulates in the breathing zone, approaches or exceeds the "Exposure Standard" (or ES), respiratory protection is required.

Degree of protection varies with both face-piece and Class of filter; the nature of protection varies with Type of filter.

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	A-AUS	-	A-PAPR-AUS / Class 1
up to 50 x ES	-	A-AUS / Class 1	-
up to 100 x ES	-	A-2	A-PAPR-2 ^

^ - Full-face

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO₂), G = Agricultural chemicals, K = Ammonia(NH₃), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content. The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	White opaque viscous highly flammable liquid with characteristic of flavour odour; not miscible with water.		
Physical state	Liquid	Relative density (Water = 1)	1.04
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Applicable	Decomposition temperature	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	1500-3500 cPs @ 25C
Initial boiling point and boiling range (°C)	106	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	16.9	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	HIGHLY FLAMMABLE.	Oxidising properties	Not Available
Upper Explosive Limit (%)	12.7 (2-propanol)	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	2.0 (2-propanol)	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water (g/L)	Immiscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	678

SECTION 10 STABILITY AND REACTIVITY

Reactivity	See section 7
Chemical stability	<ul style="list-style-type: none"> ▶ Polymerisation may occur at elevated temperatures. ▶ Polymerisation may be accompanied by generation of heat as exotherm. ▶ Process is self accelerating as heating causes more rapid polymerisation. ▶ Exotherm may cause boiling with generation of acrid, toxic and flammable vapour.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 TOXICOLOGICAL INFORMATION

Information on toxicological effects

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Inhaled	Inhalation hazard is increased at higher temperatures. Inhalation of high concentrations of gas/vapour causes lung irritation with coughing and nausea, central nervous depression with headache and dizziness, slowing of reflexes, fatigue and inco-ordination.
Ingestion	Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.
Skin Contact	The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin. Repeated exposure may cause skin cracking, flaking or drying following normal handling and use. Open cuts, abraded or irritated skin should not be exposed to this material Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.
Eye	This material can cause eye irritation and damage in some persons.
Chronic	Skin contact with the material is more likely to cause a sensitisation reaction in some persons compared to the general population.

Dentsply NUPRO 5% Sodium Fluoride White Varnish	TOXICITY	IRRITATION
	Not Available	Not Available
diurethane dimethacrylate	TOXICITY	IRRITATION
	Oral (rat) LD50: >5000 mg/kg ^[1]	Not Available
isopropanol	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: 12800 mg/kg ^[2]	Eye (rabbit): 10 mg - moderate
	Inhalation (rat) LC50: 32000 ppm/8hr ^[2]	Eye (rabbit): 100 mg - SEVERE
	Oral (rat) LD50: 5000 mg/kg ^[2]	Eye (rabbit): 100mg/24hr-moderate Skin (rabbit): 500 mg - mild
sodium fluoride	TOXICITY	IRRITATION
	dermal (rat) LD50: >2000 mg/kg ^[1] Oral (rat) LD50: >25<2000 mg/kg ^[1]	Eye (rabbit): 20 mg/24h-moderate
titanium dioxide	TOXICITY	IRRITATION
	Inhalation (rat) LC50: >2.28 mg/l/4hr ^[1]	Skin (human): 0.3 mg /3D (int)-mild *
	Inhalation (rat) LC50: >3.56 mg/l/4hr ^[1]	
	Inhalation (rat) LC50: >6.82 mg/l/4hr ^[1] Oral (rat) LD50: >2000 mg/kg ^[1]	

Legend: 1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. * Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

DIURETHANE DIMETHACRYLATE	The following information refers to contact allergens as a group and may not be specific to this product. Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. UV (ultraviolet) / EB (electron beam) acrylates are generally of low toxicity. UV/EB acrylates are divided into two groups the "stenomeric" and "eurymeric" acrylates. Stenomeric acrylates are usually more hazardous than the eurymeric substances. Where no "official" classification for acrylates and methacrylates exists, there have been cautious attempts to create classifications in the absence of contrary evidence. For example Monoalkyl or monoarylestere of acrylic acids should be classified as R36/37/38 and R51/53 Monoalkyl or monoaryl esters of methacrylic acid should be classified as R36/37/38 * Possible carcinogen; possible sensitizer; possible irreversible effects * Polysciences MSDS
ISOPROPRANOL	Isopropanol is irritating to the eyes, nose and throat but generally not to the skin. Prolonged high dose exposure may also produce depression of the central nervous system and drowsiness. Few have reported skin irritation. It can be absorbed from the skin or when inhaled.
TITANIUM DIOXIDE	Exposure to titanium dioxide is via inhalation, swallowing or skin contact. When inhaled, it may deposit in lung tissue and lymph nodes causing dysfunction of the lungs and immune system. Absorption by the stomach and intestines depends on the size of the particle. It penetrated only the outermost layer of the skin, suggesting that healthy skin may be an effective barrier. WARNING: This substance has been classified by the IARC as Group 2B: Possibly Carcinogenic to Humans. * IUCLID
DIURETHANE DIMETHACRYLATE & SODIUM FLUORIDE	Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia.
ISOPROPRANOL & TITANIUM DIOXIDE	The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.
ISOPROPRANOL & SODIUM FLUORIDE	The substance is classified by IARC as Group 3: NOT classifiable as to its carcinogenicity to humans. Evidence of carcinogenicity may be inadequate or limited in animal testing.

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SODIUM FLUORIDE & TITANIUM DIOXIDE	The material may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.		
Acute Toxicity	✓	Carcinogenicity	⊘
Skin Irritation/Corrosion	⊘	Reproductivity	⊘
Serious Eye Damage/Irritation	✓	STOT - Single Exposure	✓
Respiratory or Skin sensitisation	✓	STOT - Repeated Exposure	⊘
Mutagenicity	⊘	Aspiration Hazard	⊘

Legend: ✗ – Data available but does not fill the criteria for classification
✓ – Data available to make classification
⊘ – Data Not Available to make classification

SECTION 12 ECOLOGICAL INFORMATION

Toxicity

Dentsply NUPRO 5% Sodium Fluoride White Varnish	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable

diurethane dimethacrylate	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	EC50	48	Crustacea	>1.2mg/L	2
	EC50	72	Algae or other aquatic plants	>0.68mg/L	2
	NOEC	72	Algae or other aquatic plants	>0.21mg/L	2

isopropanol	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	LC50	96	Fish	183.844mg/L	3
	EC50	48	Crustacea	12500mg/L	5
	EC50	96	Algae or other aquatic plants	993.232mg/L	3
	EC29	504	Crustacea	=100mg/L	1
NOEC	5760	Fish	0.02mg/L	4	

sodium fluoride	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	LC50	96	Fish	51mg/L	2
	EC50	48	Crustacea	58mg/L	4
	EC50	96	Algae or other aquatic plants	181mg/L	1
	BCF	240	Fish	5mg/L	4
NOEC	504	Fish	4mg/L	2	

titanium dioxide	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	LC50	96	Fish	9.214mg/L	3
	EC50	48	Crustacea	>10mg/L	2
	EC50	72	Algae or other aquatic plants	5.83mg/L	4
	EC20	72	Algae or other aquatic plants	1.81mg/L	4
NOEC	336	Fish	0.089mg/L	4	

Legend: *Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data*

DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
isopropanol	LOW (Half-life = 14 days)	LOW (Half-life = 3 days)
sodium fluoride	LOW	LOW
titanium dioxide	HIGH	HIGH

Bioaccumulative potential

Ingredient	Bioaccumulation
isopropanol	LOW (LogKOW = 0.05)
sodium fluoride	LOW (BCF = 6.4)
titanium dioxide	LOW (BCF = 10)

Mobility in soil

Ingredient	Mobility
isopropanol	HIGH (KOC = 1.06)
sodium fluoride	LOW (KOC = 14.3)
titanium dioxide	LOW (KOC = 23.74)

SECTION 13 DISPOSAL CONSIDERATIONS

Waste treatment methods

Product / Packaging disposal

- ▶ **DO NOT** allow wash water from cleaning or process equipment to enter drains.
- ▶ It may be necessary to collect all wash water for treatment before disposal.
- ▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.
- ▶ Where in doubt contact the responsible authority.
- ▶ Recycle wherever possible.
- ▶ Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.
- ▶ Dispose of by: burial in a land-fill specifically licensed to accept chemical and / or pharmaceutical wastes or incineration in a licensed apparatus (after admixture with suitable combustible material).
- ▶ Decontaminate empty containers.

SECTION 14 TRANSPORT INFORMATION

Labels Required



Marine Pollutant

NO

HAZCHEM

2YE

Land transport (ADG)

UN number	UN proper shipping name	Transport hazard class(es)	Packing group	Environmental hazard	Special precautions for user
1219	ISOPROPANOL (ISOPROPYL ALCOHOL)	Class : 3 Subrisk : Not Applicable	II	Not Applicable	Special provisions : Not Applicable Limited quantity : 1 L
1219	Isopropanol; isopropyl alcohol	ICAO/IATA Class : 3 ICAO / IATA Subrisk : Not Applicable ERG Code : 3L	II	Not Applicable	Special provisions : Not Applicable Cargo Only Packing Instructions : 364 Cargo Only Maximum Qty / Pack : 60 L Passenger and Cargo Packing Instructions : 353 Passenger and Cargo Maximum Qty / Pack : 5 L Passenger and Cargo Limited Quantity Packing Instructions : Y341 Passenger and Cargo Limited Maximum Qty / Pack : 1 L

Air transport (ICAO-IATA / DGR)

UN number	UN proper shipping name	Transport hazard class(es)	Packing group	Environmental hazard	Special precautions for user
1219	ISOPROPANOL (ISOPROPYL ALCOHOL)	ICAO/IATA Class : 3 ICAO / IATA Subrisk : Not Applicable ERG Code : 3L	II	Not Applicable	Special provisions : Not Applicable Cargo Only Packing Instructions : 364 Cargo Only Maximum Qty / Pack : 60 L Passenger and Cargo Packing Instructions : 353 Passenger and Cargo Maximum Qty / Pack : 5 L Passenger and Cargo Limited Quantity Packing Instructions : Y341 Passenger and Cargo Limited Maximum Qty / Pack : 1 L
1219	Isopropanol; isopropyl alcohol	ICAO/IATA Class : 3 ICAO / IATA Subrisk : Not Applicable ERG Code : 3L	II	Not Applicable	Special provisions : Not Applicable Cargo Only Packing Instructions : 364 Cargo Only Maximum Qty / Pack : 60 L Passenger and Cargo Packing Instructions : 353 Passenger and Cargo Maximum Qty / Pack : 5 L Passenger and Cargo Limited Quantity Packing Instructions : Y341 Passenger and Cargo Limited Maximum Qty / Pack : 1 L

Sea transport (IMDG-Code / GGVSee)

UN number	UN proper shipping name
1219	ISOPROPANOL (ISOPROPYL ALCOHOL)

Dentsply NUPRO 5% Sodium Fluoride White Varnish

Transport hazard class(es)	IMDG Class	3
	IMDG Subrisk	Not Applicable
Packing group	II	
Environmental hazard	Not Applicable	
Special precautions for user	EMS Number	F-E , S-D
	Special provisions	Not Applicable
	Limited Quantities	1 L

Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

SECTION 15 REGULATORY INFORMATION

Safety, health and environmental regulations / legislation specific for the substance or mixture

DIURETHANE DIMETHACRYLATE(72869-86-4) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

ISOPROPANOL(67-63-0) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards

Australia Hazardous Substances Information System - Consolidated Lists

Australia Inventory of Chemical Substances (AICS)

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

SODIUM FLUORIDE(7681-49-4) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards

Australia Hazardous Substances Information System - Consolidated Lists

Australia Inventory of Chemical Substances (AICS)

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

TITANIUM DIOXIDE(13463-67-7) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards

Australia Inventory of Chemical Substances (AICS)

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

National Inventory	Status
Australia - AICS	Y
Canada - DSL	N (diurethane dimethacrylate)
Canada - NDSL	N (sodium fluoride; isopropanol)
China - IECSC	Y
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (diurethane dimethacrylate; sodium fluoride; isopropanol)
Korea - KECI	Y
New Zealand - NZIoC	Y
Philippines - PICCS	Y
USA - TSCA	Y
Legend:	Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)

SECTION 16 OTHER INFORMATION

Other information

Ingredients with multiple cas numbers

Name	CAS No
diurethane dimethacrylate	72869-86-4, 41137-60-4
titanium dioxide	13463-67-7, 1317-70-0, 1317-80-2, 12188-41-9, 1309-63-3, 100292-32-8, 101239-53-6, 116788-85-3, 12000-59-8, 12701-76-7, 12767-65-6, 12789-63-8, 1344-29-2, 185323-71-1, 185828-91-5, 188357-76-8, 188357-79-1, 195740-11-5, 221548-98-7, 224963-00-2, 246178-32-5, 252962-41-7, 37230-92-5, 37230-94-7, 37230-95-8, 37230-96-9, 39320-58-6, 39360-64-0, 39379-02-7, 416845-43-7, 494848-07-6, 494848-23-6, 494851-77-3, 494851-98-8, 55068-84-3, 55068-85-4, 552316-51-5, 62338-64-1, 767341-00-4, 97929-50-5, 98084-96-9

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

PC – TWA: Permissible Concentration-Time Weighted Average

PC – STEL: Permissible Concentration-Short Term Exposure Limit

IARC: International Agency for Research on Cancer

Continued...

Dentsply NUPRO 5% Sodium Fluoride White Varnish

ACGIH: American Conference of Governmental Industrial Hygienists

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit,

IDLH: Immediately Dangerous to Life or Health Concentrations

OSF: Odour Safety Factor

NOAEL :No Observed Adverse Effect Level

LOAEL: Lowest Observed Adverse Effect Level

TLV: Threshold Limit Value

LOD: Limit Of Detection

OTV: Odour Threshold Value

BCF: BioConcentration Factors

BEI: Biological Exposure Index

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TEL (+61 3) 9572 4700.

DENTSPLY International

DENTSPLY PROFESSIONAL

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: 12 December 2012

Document Number: 130208

Date Revised: 03/08/2013

Revision Number: 1

1. PRODUCT IDENTIFICATION

Trade Name (as labeled): NUPRO® 5% Sodium Fluoride White Varnish

Product Identifier (Part/Item Number): 130210, 130211, 130212, 130213, 130214, 130215

U.N. Number: UN1219

U.N. Dangerous Goods Classification: 3

Recommended Use: One-step application that reduces dentinal hypersensitivity

Restrictions on Use: For Professional Use Only

Manufacturer/Supplier Name: DENTSPLY Professional

Manufacturer/Supplier Address: 1301 Smile Way
York, PA 17404

Manufacturer/Supplier Telephone Number: 800-989-8826 or 717-767-8502 (Product Information)

Transportation Emergency Contact Telephone Number: 800-424-9300 Chemtrec

Email address: ProfessionalMSDS@dentsply.com

2. HAZARD(S) IDENTIFICATION

Hazard/Danger Classification:

Health	Environmental	Physical
Acute Toxicity Category 4 Skin Sensitizer Category 1 Eye Irritant Category 2 Specific Target Organ Toxicity –Single Exposure Category 3	Non-Hazardous	Flammable Liquid Category 2

GHS Labeling Elements: Contains 2-Propanol and Sodium Fluoride



Signal Word: Danger

Hazard Statements

H225 Highly flammable liquid and vapor
H302 Harmful if swallowed
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.

Precautionary Statements

Prevention:

P210 Keep away from heat, sparks, open flames, and hot surfaces. - No smoking.
P233 Keep container tightly closed.
P261 Avoid breathing vapors.
P264 Wash exposed skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P271 Use only outdoors or in a well-ventilated area.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing, eye protection, and face protection.

Response:

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 If eye irritation persists: Get medical attention
P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P363 Wash contaminated clothing before reuse.
P304+P340 IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.
P312 Call a POISON CENTER or doctor/physician if you feel unwell.
P301+P312 IF SWALLOWED: Call a POISON CENTER, doctor if you feel unwell
P330 Rinse mouth.
P370+P378 In case of fire: Use carbon dioxide, alcohol-resistant foam, dry chemical and water spray to extinguish.

Storage:

P403+P235 Store in a well-ventilated place. Keep cool.
P405 Store locked up.

Disposal:

P501 Dispose of contents and container in accordance with local and national regulations.

3. COMPOSITION AND INFORMATION ON INGREDIENTS





Hazardous Components	C.A.S. #	EINECS #	Substance Classification	WT %
Urethane Dimethacrylate Resin	72869-86-4	276-957-5	Skin Sens.1 (H317)	30-40
2-Propanol	67-63-0	200-661-7	Flam. Liq. 2 (H225), Eye Irrit. 2 (H319), STOT SE 3 (H336)	20-30
Sodium Fluoride	7681-49-4	231-667-8	Acute Tox. 3 (H301), Eye Irrit. 2 (H319), Skin Irrit. 2 (H315)	4-6
Titanium Dioxide	13463-67-7	236-675-5	Carc. 2 (H351)	<1

Note: The Titanium Dioxide in this product is not unbound or respirable. Therefore, no warning is required.

4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions
Eye	Immediately flush victim's eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention if irritation persists.
Skin	Remove contaminated clothing. Wash skin with soap and water. Get medical attention if irritation develops. Launder clothing before re-use.
Inhalation	Remove victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. If breathing has stopped, administer artificial respiration. Get immediate medical attention.
Ingestion	Rinse out mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious or drowsy person. Get immediate medical attention.
Most important symptoms of exposure	May cause eye and skin irritation. May cause skin sensitization. May be harmful if swallowed. Vapors may cause drowsiness and dizziness.
Note to Physicians (Treatment, Testing, and Monitoring)	
Treat symptomatically.	



5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media:	Use carbon dioxide, alcohol-resistant foam, dry chemical and water spray.		
Fire Fighting Procedures:	Cool fire exposed containers with water spray.		
Specific Hazards Arising from the Chemical:	Highly flammable liquid and vapor. Closed containers exposed to heat from fire may build pressure and explode.		
Precautions for Fire Fighters:	Firefighters should wear full emergency equipment and approved positive pressure self-containing breathing apparatus.		
Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	HANDS	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: Remove all ignition sources such as open flames, spark producing equipment, pilot lights, etc. Avoid contact with skin, eyes or clothing. Wear appropriate protective clothing as described in Section 8.
Environmental Precautions: Prevent entry into sewers and waterways. Report releases as required by local, state, and national authorities.
Methods and Materials for Containment and Clean-up: Clean up with absorbent material and remove residue with alcohol damp wipe. Rinse spill area with water.

Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE	HANDS	RESPIRATORY	THERMAL
			

7. HANDLING AND STORAGE

Precautions for Safe Handling: Avoid contact with the eyes, skin and clothing. Avoid breathing vapors. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Wash thoroughly after handling. Keep away from heat, sparks, flames, and other sources of ignition.



Empty containers retain product residues can be hazardous. Follow all SDS precautions when handling empty containers.

Conditions for Safe Storage: Store in a dry, well ventilated area away from heat, direct sunlight and all sources of ignition. Store away from acids and oxidizing agents. Keep out of reach of children.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:

Urethane Dimethacrylate Resin	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
2-Propanol	United States	200 ppm TWA, 400 ppm STEL ACGIH TLV 400 ppm TWA OSHA PEL
	Germany	200 ppm TWA, 40 ppm STEL DFG MAK
	United Kingdom	400 ppm TWA, 500 ppm STEL UK OEL
	European Union	None Established
Sodium Fluoride (As Flouride)	United States	2.5 mg/m3 TWA ACGIH TLV 2.5 mg/m3 TWA OSHA PEL
	Germany	1 mg/m3 (Inhalable) TWA, 4 mg/m3 STEL DFG MAK
	United Kingdom	2.5 mg/m3 TWA UK OEL
	European Union	2.5 mg/m3 TWA EU OEL

Titanium Dioxide	United States	10 mg/m ³ TWA ACGIH TLV 15 mg/m ³ (Total Dust) TWA OSHA PEL	
	Germany	None Established	
	United Kingdom	10 mg/m ³ (Inhalable), 4 mg/m ³ (Respirable) TWA UK OEL	
	European Union	None Established	
Biological Exposure Limits: Sodium Fluoride (as fluorides) - Prior to shift 3 mg/g creatinine; End of shift 10 mg/g creatinine			
Appropriate Engineering Controls: Use with adequate general or local exhaust ventilation to maintain exposures below the occupational exposure limits.			
Individual Protection Measures (PPE) Specific Eye/face Protection: Chemical safety goggles should be worn if needed to avoid eye contact. Specific Skin Protection: Wear impervious gloves such as natural rubber or neoprene if needed to avoid skin contact. Consult glove supplier for thickness and breakthrough times. Specific Respiratory Protection: None should be needed under normal use. If exposure limits are exceeded an approved respirator or supplied air respirator appropriate should be used. Respirator selection and use should be based on contaminant type, form and concentration. Follow applicable regulations and good Industrial Hygiene practice. Specific Thermal Hazards: None required.			
Recommended Personal Protective Equipment			
EYES/FACE	HANDS	RESPIRATORY	THERMAL
			
Environmental Exposure Controls: None required for normal use.			
General Hygiene Considerations and Work Practices: Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling. Remove and launder contaminated clothing before reuse.			
Protective Measures During Repair and Maintenance of Contaminated Equipment: Wear appropriate protective clothing and equipment.			

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	White opaque viscous liquid	Explosive limits:	LEL: 2.0 % (2-Propanol) UEL: 12.7 % @ 93°C (200°F) (2-Propanol)
Odor:	Fruit odor	Vapor pressure:	Not applicable
Odor threshold:	Not determined	Vapor density:	Not applicable
pH:	Not determined	Relative density:	1.04 g/mL

Melting/freezing point:	Not determined	Solubility:	Insoluble in water
Initial boiling point and range:	106°C (222.8°F)	Partition coefficient: n-octanol/water:	Not determined
Flash point:	16.9°C (62.4°F) Method: Closed Cup	Auto-ignition temperature:	Not determined
Evaporation rate:	Not applicable	Decomposition temperature:	Not determined
Flammability:	Highly flammable under fire conditions.	Viscosity:	1,500-3,500 cP @ 25°C
Explosive Properties:	None	Oxidizing Properties:	None

10. STABILITY AND REACTIVITY

Reactivity: None known.

Chemical Stability: Stable.

Possibility of Hazardous Reactions: Contact with acids liberates toxic gas.

Conditions to Avoid: Keep away from heat, sparks, flames and other sources of ignition.

Incompatible materials: Avoid acids and oxidizing materials.

Hazardous Decomposition Products: Thermal decomposition may release carbon monoxide, carbon dioxide, phosgene, hydrogen chloride and/or hydrogen fluoride.

11. TOXICOLOGICAL INFORMATION

Potential Health Effects:

Eyes: May cause moderate irritation with redness, tearing and blurred vision.

Skin: Prolonged or repeated contact may cause mild skin irritation redness, rash and swelling. May cause allergic skin reaction (sensitization).

Ingestion: Ingestion may cause irritation to the mouth, throat and stomach with abdominal pain and nausea. May cause gastrointestinal irritation and central nervous system depression with symptoms similar to those described under inhalation.

Inhalation: Inhalation may cause nose and throat irritation with the possibility of central nervous system depression. Symptoms of central nervous system depression include headache, dizziness, drowsiness, nausea and unconsciousness.

Chronic Health Effects: Prolonged overexposure to sodium fluorides may cause fluorosis with symptoms of joint pain, limited mobility, brittle bones, calcification of ligaments, bone and teeth abnormalities and mottled tooth enamel.

Carcinogenicity: A 2-year study in rats found a weak, equivocal fluoride-related increase in the occurrence of osteosarcomas in male rats, and no evidence of carcinogenicity in female rats or male or female mice. The weight of the evidence indicates that fluoridation of water does not increase the risk of developing cancer. IARC has determined that the carcinogenicity of fluoride to humans is not classifiable. This product contains small amount of titanium dioxide, which is listed by IARC as a suspected carcinogen (Group 2B). Titanium dioxide only presents a risk of cancer by inhalation of very fine dust. In this product, the titanium dioxide is incorporated into a viscous liquid and is not present as a respirable dust. There is no exposure to respirable titanium dioxide dust in the normal use of this product. None of the other components of this product are listed as carcinogens by OSHA, IARC, ACGIH, the EU CLP, or NTP.

Mutagenicity: Sodium fluoride was negative in the AMES test but was positive a mouse lymphoma cells assay. Sodium fluoride did not induce DNA strand breaks in testicular cells of rats treated in-vivo and did not cause chromosomal aberrations in bone marrow or testicular cells or sister chromatid exchanges in bone marrow cells of mice treated in-vivo.

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

Acute Toxicity Data:

Urethane dimethacrylate Resin: Oral Rat LD50- >5000 mg/kg

2-Propanol: Oral rat LD50- 5045 mg/kg; Inhalation rat LC50 – 16000 ppm /8hr; Skin rabbit LD50- 12800 mg/kg

Sodium Fluoride: Oral Rat LD50-32 mg/kg

Titanium dioxide: Oral rat LD50 - >20000 mg/kg; Skin hamster LD50 ->10000 mg/kg

Reproductive Toxicity Data: Sodium Fluoride: In a 75 day reproductive study with rats, doses of 4.5 ppm and 9.0 ppm showed a significant decrease in sperm count, sperm motility, sperm viability and sperm function. However, other animal studies, including two-generation studies, have not found alterations in serum hormone levels in male rats, testicular histopathology, sperm morphology, or fertility. None of the available laboratory animal studies examined reproductive toxicity at low fluoride doses. The inadequate human studies and conflicting animal studies do not allow for an assessment of the potential of fluoride to induce reproductive effects in humans. Animal studies have not found increases in the incidences of birth defects in the absence of maternal toxicity; at doses that caused maternal toxicity (decreases in body weight gain and food consumption), increases in abnormalities were found.

Specific Target Organ Toxicity (STOT):

Single Exposure: Sodium Fluoride: In a human exposure study, adults were given 250 mg. Effects included nausea, vomiting, epigastric distress, salivation and itching of the hands and feet. In an acute study, dogs were infused with an acute dose of 36 mg/kg. Death occurred in less than 65 minutes. Principal effects included a decline in blood pressure, heart rate, central nervous system activity, vomiting and defecation.

Repeated Exposure: Sodium Fluoride: Brain, liver, kidneys and muscles demonstrate significant changes in essential trace element levels in adult female mice given 30, 60 and 120 ppm sodium fluoride in drinking water. Rats exposed to sodium fluoride in drinking water for 2 months developed thyroid effects; LOAEL 0.5 mg/kg/day. Mice exposed to sodium fluoride in drinking water for 4 weeks showed increased bone formation. LOAEL 0.8 mg/kg/day.

12. ECOLOGICAL INFORMATION

Toxicity:

Urethane dimethacrylate Resin: 48hr EC50 Daphnia magna - >1.2 mg/l; 72 hr EC50 Desmodesmus subspicatus (algae)- >0.68 mg/L (growth rate)

2-Propanol: 96 hr LC50 Fathead minnow – 9640 mg/L; 24 hr EC50 Water flea- 9714 mg/L

Sodium Fluoride: 96 hr LC50 Oncorhynchus mykiss (Rainbow trout) - 83.7 mg/L, 48 hr EC50 Daphnia magna - 98 mg/L

Persistence and Degradability: Biodegradation is not applicable to inorganic substances such as sodium fluoride. Urethane dimethacrylate Resin: 22% after 28 days - Not readily biodegradable. 2-Propanol: 95% after 21 days- Readily biodegradable.

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

Other Adverse Effects: No data available

Results of PBT/vPvB Assessment: No data available

13. DISPOSAL CONSIDERATIONS

Regulations: Dispose in accordance with all national and local regulations.

Properties (Physical/Chemical) Affecting Disposal: None currently known.

Waste Treatment Recommendations: Dispose in accordance with national and local regulations.

14. TRANSPORT INFORMATION

UN Number:	ADR/RID: UN1219	IMDG: UN1219	IATA: UN1219	DOT: UN1219
UN proper shipping name:	ADR/RID: Isopropanol Solution IMDG: Isopropanol Solution IATA: Isopropanol Solution DOT: Isopropanol Solution			
Transport hazard class(es):	ADR/RID: 3	IMDG: 3	IATA: 3	DOT: 3
Packaging group:	ADR/RID: II	IMDG: II	IATA: II	DOT: II
Environmental hazards:	ADR/RID: No	IMDG Marine pollutant: No	IATA: No	DOT: No
Special precautions for user: Not applicable				

15. REGULATORY INFORMATION

U.S. Federal Regulations

US OSHA Hazard Classification: Irritant, Sensitizer, Flammable liquid

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product has a Reportable Quantity (RQ) of 16,666 lbs (based on the RQ of 1,000 lbs for Sodium Fluoride present at 6%). Report spills required under federal, state and local regulations.

Toxic Substances Control Act (TSCA): This product is a medical device and not subject to chemical notification.

Clean Water Act (CWA): This material is not regulated under the Clean Water Act

Clean Air Act (CAA): This material is not regulated under the Clean Air Act

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories:

Immediate Hazard:	Yes	Pressure Hazard:	No
Delayed Hazard:	No	Reactivity Hazard:	No
Fire Hazard:	Yes		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372): None

Components	C.A.S. #	WT %
None		

State Regulations

California: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity:

Components	C.A.S. #	WT %
None		

Note: The Titanium Dioxide in this product is not unbound or respirable. Therefore, no warning is required.

International Regulations

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification.

Canadian Workplace Hazardous Materials Information System (WHMIS): Medical devices are not subject to WHMIS.

This MSDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the MSDS contains all of the information required by the CPR.

European Inventory of Existing Chemicals (EINECS): This product is a medical device and not subject to chemical notification requirements.

EU REACH: All components requiring registration have been pre-registered.

Australian Inventory of Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Japanese Existing and New Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a medical device and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health -2 Flammability - 3 Reactivity - 0

Full text of Classification abbreviations used in Section 2 and 3:

Acute Tox. 3 Acute Toxicity Category 3

Acute Tox. 4 Acute Toxicity Category 4

Carc. 2 Carcinogen Category 2

Eye Irrit. 2 Eye Irritant Category 2
Flam. Liq. 2 Flammable Liquid Category 2
Skin Irrit. 2 Skin Irritant Category 2
Skin Sens. 1 Skin Sensitizer Category 1
STOT SE 3 Specific Target Organ Toxicity Single Exposure Category 3
H225 Highly Flammable Liquid and Vapor
H301 Toxic if swallowed.
H302 Harmful if swallowed.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.
H351 Suspected of causing cancer.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.

Supersedes: Revision 0 Date Issued December 12, 2012

Revision Summary: Revision 1 March 08, 2013- Section 1: Emergency Contact Telephone Number was revised to Transportation Emergency Contact Telephone Number