

Material Safety Data Sheet Cover-Sheet – This page provides additional New Zealand specific information for this product and must be read in conjunction with the Safety Data Sheet (SDS) attached

Product Name: Duraphat

Manufacturer: Colgate-Palmolive Ltd.

SDS Expiry: 19 February 2025

Supplier Details: Henry Schein New Zealand
243-249 Bush Road, Rosedale, Auckland, 0632
PO Box 101 140, North Shore, Auckland 0745
Ph. 0800 808 855
www.henryschein.co.nz

Emergency Contacts: Poisons/Hazardous Chemical Info Centre –
0800POISON/0800764766 (24 Hours)
Phone 111 for Fire, Ambulance or Police

HSNO Class/Category: 3 / 6

HSNO Group Standard: Dental Products Flammable Group Standard 2020 HSR002556

Statements/Pictograms: As per attached Safety Data Sheet (SDS)

Date Prepared: This coversheet was prepared – June 2023

This SDS coversheet has been produced by Henry Schein NZ and has been prepared in accordance with NZ EPA advice on making overseas SDS compliant to HSNO Act. The above information is based on the present state of our knowledge of the product at the time of publication. It is given in good faith, no warranty is implied with respect to the quality or the specifications of the product. Users must satisfy that the product is entirely suitable for their purpose. The SDS and this coversheet may be revised from time to time, please ensure you have a current copy.

Duraphat 22,600 ppmF Sodium Fluoride Varnish

This industrial Safety Data Sheet is not intended for consumers and does not address consumer use of the product. For information regarding consumer applications of this product, refer to the product label.

Version	Revision Date:	SDS Number:	Date of last issue: 09.08.2019
2.6	19.02.2020	660000004359	Date of first issue: 05.02.2018

Section 1: Identification

Product name : Duraphat 22,600 ppmF Sodium Fluoride Varnish

Product code : B06702700003
: 200000047777

Manufacturer or supplier's details

Address : Colgate-Palmolive Ltd.
Level 4, 45 Knights Road, Lower Hutt
P.O.Box 38077, Wellington Mail centre
Wellington, 5045, New Zealand.
Telephone : CONSUMER AFFAIRS: - NZ 0800 441 740 (Mon – Fri 9 - 7)

Emergency telephone number : CHEMTREC New Zealand +(64)-98010034
Global-CHEMTREC- +1 703-741-5970

Recommended use of the chemical and restrictions on use



Recommended use : Topical fluoride treatment

Section 2: Hazard identification

GHS Classification

Flammable liquids : Category 3
Acute toxicity (Oral) : Category 4
Serious eye damage/eye irritation : Category 2A
Skin sensitisation : Category 1

GHS label elements

Hazard pictograms :  

Signal word : Warning

Hazard statements : H226 Flammable liquid and vapour.
H302 Harmful if swallowed.

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----------------	------------------------------	-----------------------------	---

H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.

Precautionary statements

:

Prevention:

P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P233 Keep container tightly closed.
P240 Ground/bond container and receiving equipment.
P241 Use explosion-proof electrical/ ventilating/ lighting equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/ eye protection/ face protection.

Response:

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

Storage:

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

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

None known.

Section 3: Composition/information on ingredients

Components

Chemical name	CAS-No.	Concentration (% w/w)
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2.6	19.02.2020	660000004359	Date of first issue: 05.02.2018

COLOPHONIUM	8050-09-7	>= 30 -< 40
ETHANOL (ETHYL ALCOHOL)	64-17-5	>= 20 -< 30
Sodium Fluoride	7681-49-4	>= 3 -< 5

Section 4: First-aid measures

- General advice : If poisoning occurs, immediately contact a doctor or Poisons Information Centre (Phone Australia 131126; New Zealand 0800 764 766), and follow the advice given.
- If inhaled : If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.
- In case of skin contact : If skin irritation persists, call a physician.
If on skin, rinse well with water.
If on clothes, remove clothes.
- In case of eye contact : Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.
Administer milk but do not induce vomiting.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
- Most important symptoms and effects, both acute and delayed : Harmful if swallowed.
May cause an allergic skin reaction.
Causes serious eye irritation.

Section 5: Fire-fighting measures

- Suitable extinguishing media : Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire-fighting : Do not allow run-off from fire fighting to enter drains or water courses.
- Hazardous combustion products : No hazardous combustion products are known

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----------------	------------------------------	-----------------------------	---

- Specific extinguishing methods : Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. For safety reasons in case of fire, cans should be stored separately in closed containments. Use a water spray to cool fully closed containers.
- Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

Section 6: Accidental release measures

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas.
- Environmental precautions : Prevent product from entering drains. Prevent further leakage or spillage if safe to do so. If the product contaminates rivers and lakes or drains inform respective authorities.
- Methods and materials for containment and cleaning up : Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

Section 7: Handling and storage

- Advice on protection against fire and explosion : Do not spray on a naked flame or any incandescent material. Take necessary action to avoid static electricity discharge (which might cause ignition of organic vapours). Keep away from open flames, hot surfaces and sources of ignition.
- Advice on safe handling : Avoid formation of aerosol. Do not breathe vapours/dust. Avoid exposure - obtain special instructions before use. Avoid contact with skin and eyes. For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area. Take precautionary measures against static discharges. Provide sufficient air exchange and/or exhaust in work rooms. Open drum carefully as content may be under pressure. Dispose of rinse water in accordance with local and national regulations. Persons susceptible to skin sensitisation problems or asthma,

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----------------	------------------------------	-----------------------------	---

allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

- Hygiene measures : When using do not eat or drink.
When using do not smoke.
Wash hands before breaks and at the end of workday.
- Conditions for safe storage : No smoking.
Keep container tightly closed in a dry and well-ventilated place.
Containers which are opened must be carefully resealed and kept upright to prevent leakage.
Observe label precautions.
Electrical installations / working materials must comply with the technological safety standards.
Store below 25°C
- Further information on storage stability : No decomposition if stored and applied as directed.

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
ETHANOL (ETHYL ALCOHOL)	64-17-5	WES-TWA	1,000 ppm 1,880 mg/m ³	NZ OEL
		STEL	1,000 ppm	ACGIH
Sodium Fluoride	7681-49-4	WES-TWA	2.5 mg/m ³ (Fluorine)	NZ OEL
Further information: Exposure can also be estimated by biological monitoring				
		TWA	2.5 mg/m ³ (Fluorine)	ACGIH

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis
Sodium Fluoride	7681-49-4	Fluoride (Fluorine)	Urine	Prior to shift	2 mg/l	NZ BEI
		Fluoride (Fluorine)	Urine	End of shift	3 mg/l	NZ BEI
		Fluoride (Fluorine)	Urine	Prior to shift (16 hours after)	2 mg/l	ACGIH BEI

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				exposure ceases)		
		Fluoride (Fluorine)	Urine	End of shift (As soon as possible after exposure ceases)	3 mg/l	ACGIH BEI

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

Remarks : The suitability for a specific workplace should be discussed with the producers of the protective gloves.

Eye protection : Eye wash bottle with pure water
 Tightly fitting safety goggles
 Wear face-shield and protective suit for abnormal processing problems.

Skin and body protection : Impervious clothing
 Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Section 9: Physical and chemical properties

Appearance : paste

Colour : brown

pH : No data available

Flash point : 28.88 °C

Density : 1.0215 g/cm³

Section 10: Stability and reactivity

Reactivity : No decomposition if stored and applied as directed.

Chemical stability : No decomposition if stored and applied as directed.

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Possibility of hazardous reactions : No decomposition if stored and applied as directed.
Vapours may form explosive mixture with air.

Conditions to avoid : Heat, flames and sparks.

Incompatible materials : No data available

Hazardous decomposition products : No data available

Section 11: Toxicological information

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 1,643 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

COLOPHONIUM:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

ETHANOL (ETHYL ALCOHOL):

Acute oral toxicity : LD50 (Rat): 10,470 mg/kg

Acute inhalation toxicity : LC50 (Rabbit): 124.7 mg/l
Exposure time: 4 h
Test atmosphere: No information available.
Method: No information available.

Acute dermal toxicity : LD50 (Rat): > 15,800 mg/kg
Method: No information available.

Sodium Fluoride:

Acute oral toxicity : LD50 (Rat): 177 - 272 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402



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Skin corrosion/irritation

Not classified based on available information.

Components:

COLOPHONIUM:

Method : OECD Test Guideline 404
Result : No skin irritation

ETHANOL (ETHYL ALCOHOL):

Result : No skin irritation

Sodium Fluoride:

Result : Severe skin irritation

Remarks : May cause skin irritation in susceptible persons.

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

COLOPHONIUM:

Species : Rabbit
Result : No eye irritation
GLP : yes

ETHANOL (ETHYL ALCOHOL):

Species : Rabbit
Result : Moderate eye irritation

Sodium Fluoride:

Result : Irritation to eyes, reversing within 21 days

Remarks : May cause irreversible eye damage.

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

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Components:

COLOPHONIUM:

Species : Humans
Assessment : May cause sensitisation by skin contact.

ETHANOL (ETHYL ALCOHOL):

Exposure routes : Inhalation
Remarks : No data available

Result : Dermal
: Does not cause skin sensitisation.

Sodium Fluoride:

Exposure routes : Inhalation
Result : Does not cause respiratory sensitisation.

: Dermal
: Does not cause skin sensitisation.

Chronic toxicity

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

Components:

Sodium Fluoride:

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

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Further information

Product:

Remarks : This product has not been tested as a whole. However, this formula was reviewed by expert toxicologists in the Product Safety Assurance Department of Colgate-Palmolive and is determined to be safe for its intended use. This review has taken into consideration available safety-related information including information on individual ingredients, similar formulas and potential ingredient interactions. This review is a component of the hazard determination used to prepare the statements in Section 2 of the SDS.

Section 12: Ecological information

Ecotoxicity

Components:

COLOPHONIUM:

Toxicity to fish : LC50: 1.7 mg/l

Toxicity to daphnia and other aquatic invertebrates : LC50: 1.6 mg/l

Toxicity to algae/aquatic plants : EC50: 16.6 mg/l

ETHANOL (ETHYL ALCOHOL):

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 14.2 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna Straus): 5,012 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
Exposure time: 72 h

Toxicity to fish (Chronic toxicity) : No data available:

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : No data available:

Sodium Fluoride:

Toxicity to fish : LC50 (Cyprinodon variegatus (sheepshead minnow)): > 500 mg/l

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Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Crangon crangon (shrimp)): > 300 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Selenastrum capricornutum (green algae)): 272 mg/l
Exposure time: 96 h

Toxicity to fish (Chronic toxicity) : No data available:

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : No data available:

Persistence and degradability

Components:

COLOPHONIUM:

Biodegradability : Result: Readily biodegradable.

ETHANOL (ETHYL ALCOHOL):

Biodegradability : Result: Readily biodegradable.

Sodium Fluoride:

Biodegradability : Remarks: Not applicable

Bioaccumulative potential

Components:

ETHANOL (ETHYL ALCOHOL):

Bioaccumulation : Bioconcentration factor (BCF): 1

Partition coefficient: n-octanol/water : log Pow: -0.14

Sodium Fluoride:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : Remarks: No data available

Mobility in soil

No data available

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Other adverse effects

No data available

Section 13: Disposal considerations

Disposal methods

- Waste from residues : Do not dispose of waste into sewer.
Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.
- Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Do not re-use empty containers.
Do not burn, or use a cutting torch on, the empty drum.
-

Section 14: Transport information

- ADG (Australian Dangerous Goods) 7.6** :
UN 1993, FLAMMABLE LIQUID, N.O.S. (Ethanol), 3, III
Hazchem code: 3Y,
Hazard Index No.30
- NZS (New Zealand's Standards) 5433** :
UN 1993, FLAMMABLE LIQUID, N.O.S. (Ethanol), 3, III
Hazchem code: 3Y,
Hazard Index No.30
- IATA** :
UN 1993, FLAMMABLE LIQUID, N.O.S. (Ethanol), 3, III
- IMDG** :
UN 1993, FLAMMABLE LIQUID, N.O.S. (Ethanol), 3, III
- ADR** :
UN 1993, FLAMMABLE LIQUID, N.O.S. (Ethanol), 3, III
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Section 15: Regulatory information

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

New Zealand Medicines and Medical Devices Safety Authority Number : TT50-8316
For supply only to registered dental professionals

Section 16: Other information

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
NZ BEI : New Zealand. Biological Exposure Indices
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Tem-

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perature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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