

SAFETY DATA SHEET

PRODUCT ID: DYCLONINE HYDROCHLORIDE TOPICAL SOLUTION, USP, 0.5% AND 1%

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name:	Dyclonine Hydrochloride Topical Solution, USP, 0.5% and 1%
Brand Name:	DYCLOPRO (Dyclonine Hydrochloride Topical Solution, USP, 0.5% and 1%)
Synonyms:	4'-Butoxy-3-piperidinopropiophenone hydrochloride, C 5422, Diclona, Dyclocaium, Dyclone hydrochloride, Dyclothane, P-267, Piperidine, 1-(2-(4-butoxybenzoyl)ethyl), hydrochloride, S154, Tanaclone, 1-Propanone, 1-(4-butoxyphenyl)-3-(1-piperidiny)-, hydrochloride, 4-n-Butoxy-beta-(1-piperidyl)propiophenone hydrochloride
Manufacturer:	Novocol Pharmaceutical of Canada, Inc. 25 Wolseley Court Cambridge, Ontario, Canada N1R 6X3 519-623-4800 http://www.septodont.ca/
Supplier:	Septodont 205 Granite Run Drive Suite150 Lancaster, PA 17601 https://www.septodontusa.com/
Prepared By:	Septodont in conjunction with a third party consultant
Emergency Phone Number:	(519)-623-4800 (Monday-Friday 08:30 to 16:30)
Product Use:	Dyclonine topical solutions are indicated for anesthetizing accessible mucous membranes (e.g. mouth, pharynx, larynx, trachea, esophagus, and urethra) prior to various endoscopic procedures. Dyclonine 0.5% topical solution may also be used to block the gag reflex, to relieve the pain of oral ulcers or stomatitis and to relieve pain associated with ano-genital lesions
Date of Preparation:	January 24, 2020

SECTION 2: HAZARDS IDENTIFICATION

GHS Classification:	This product is exempt from WHMIS 2015 as a drug product. Information provided is for worker education and training purposes. <u>Equivalent</u> Classes: Mild Skin Irritation, Category 3 Serious Eye Irritation, Category 2A
<u>Equivalent</u> GHS Label Symbol:	

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GHS Hazard Statements:	WARNING Causes Serious Eye Irritation WARNING Causes Mild Skin Irritation
GHS Precautionary Statements:	Prevention P264 – Wash hands and face thoroughly after handling P280 – Wear eye protection Response P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. P332+P313 – If skin irritation occurs: get medical advice/attention P337+P313 – If eye irritation persists: get medical advice/attention Disposal P501 – Dispose of contents/container in accordance with local/provincial/federal regulations

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Identity	Concentration (per 1 ml vial)	CAS Number
Dyclonine Hydrochloride	5 or 10 mg	536-43-6
Chlorobutanol Hemihydrate	3 mg	6001-64-5
Sodium Chloride (NaCl)	8 mg	7647-14-5
10% Hydrochloric Acid (HCl)	Up to 0.1 ml (pH adjustment)	7647-01-0
Distilled Water	Remainder	7732-18-5

SECTION 4: FIRST AID MEASURES

Inhalation:	Remove patient to fresh air.
Eye Contact:	Immediately flush eyes with plenty of water for at least 15 minutes while holding eyelids open. Get medical attention, if irritation persists.
Skin Contact:	Remove contaminated clothing. Wash skin with soap and water
Ingestion:	Get immediate medical attention. Do not induce vomiting unless instructed to do so by poison control or physician.
Personal Protective Equipment for First Aid Responders:	Wear impermeable gloves to avoid skin contact (e.g. nitrile, natural rubber).

SECTION 5: FIRE FIGHTING MEASURES

Suitable extinguishing media:	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials
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Hazardous Combustion Products:	Not available
Special Protective Actions for Firefighters:	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions:	Caution should be used to prevent against ingestion and contact with eyes and skin. Wear safety glasses with side shields and impermeable gloves (i.e. nitrile, latex rubber).
Environmental precautions:	Prevent spills of large quantities from entering sewers and watercourses. Cover drains.
Methods and materials for containment and cleaning up:	Clean up spills with normal procedures used for generally non-hazardous liquids. This can include: absorb spill with inert material, then place in a chemical waste container. Clean surface thoroughly with water to remove residual contamination.

SECTION 7: HANDLING AND STORAGE

Handling Procedures and Equipment:	Avoid unintentional contact with skin and eyes. Handle with care to avoid breakage.
Storage Requirements:	Store at room temperature.
Packaging:	High density polyethylene (HDPE) bottle with a polypropylene cap
Sensitivity to Mechanical Impact:	Not sensitive
Sensitivity to Static Discharge:	Not sensitive

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:	Chemical Agent	Occupational Exposure Limits (OEL) / Guideline					
		ACGIH ^a		Ontario		Other ^e	
		TWA ^b	STEL ^c	TWA ^b	STEL ^c	TWA ^b	STEL ^c
	Dyclone Hydrochloride	Not available	Not available	Not available	Not available	Not available	Not available
	Chlorobutanol Hemihydrate	Not available	Not available	Not available	Not available	Not available	Not available
	Hydrogen Chloride	Not available	2 ppm C ^d	Not available	2 ppm C ^d	Not available	Not available

a – American Conference of Governmental Industrial Hygienists

b – Time Weighted Average

c - Short-term Exposure Limit

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d – Ceiling Limit e – Supplier Guideline	
Personal Protective Equipment (PPE):	
Gloves (specify):	Impermeable (i.e. nitrile, latex rubber) gloves should be used to minimize the potential for skin exposure
Respiratory (specify):	Not normally required
Eye (specify):	If potential for contact with eyes exists, wear safety glasses with side shields or safety goggles.
Footwear (specify):	Not normally required
Other Equipment (specify):	Wear lab coat
Engineering Controls (e.g. ventilation, enclosed process, specify):	Use with adequate ventilation – regular general ventilation is acceptable

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid
Odour and Appearance:	Clear and odourless
Odour Threshold:	Not applicable
Specific Gravity (water=1):	Approximately 1
Solubility in Water	Soluble
Co-efficient of Water/Oil Distribution:	Not available
Vapour Pressure:	Not available
Boiling Point (°C):	Not available
Melting/Freezing Point (°C):	Not available
pH:	3.4 to 3.6
Vapour Density (Air=1):	Not available
Evaporation Rate (Butyl Acetate=1):	Same as water
Flashpoint (°C) and Method:	Not flammable (water-based)
Upper Flammable Limit (%):	Not available
Lower Flammable Limit (%):	Not available
Auto-ignition Temperature (°C):	Not available
Decomposition Temperature (°C):	Not available

SECTION 10: STABILITY AND REACTIVITY

Reactivity:	Stable
Chemical Stability:	Stable, will not polymerize

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Conditions to Avoid:	Not available
Incompatible Materials:	Incompatible with compounds which react violently with water
Hazardous Decomposition Products:	Not available

SECTION 11: TOXICOLOGICAL INFORMATION

Route of Entry:	<input checked="" type="checkbox"/> Skin Contact <input checked="" type="checkbox"/> Skin Absorption <input checked="" type="checkbox"/> Eye Contact <input checked="" type="checkbox"/> Inhalation <input checked="" type="checkbox"/> Ingestion <input type="checkbox"/> Injection
Acute Toxicity:	Overexposure can cause central nervous system depression, including headaches, drowsiness, confusion Acute measures of toxicity (i.e. LD50 and LC50) are not available for this mixture. LD50 for Dyclonine Hydrochloride: 240 mg/kg oral-rabbit LD50 for Chlorobutanol: 510 mg/kg oral-rat LD50 for Hydrogen Chloride: 581 mg/kg oral-rat LC50 for Hydrogen Chloride: 9188 mg/L inhalation-rat
Skin Corrosion/Irritation:	May be irritating to the skin.
Serious Eye Damage/Irritation:	Contact with the concentrated version of the active ingredient has resulted in severe eye irritation. This product may cause a range of effects from minor to severe irritation of the eyes.
Respiratory or Skin Sensitization:	Not available
Interactive Effects:	Not available
Mutagenicity:	Not available
Irritancy to Product:	Not available
Carcinogenicity:	This product has not been listed as a carcinogen or a potential carcinogen by the ACGIH, the International Agency for Research on Cancer (IARC), the US National Toxicology Program (NTP) or the US Occupational Safety and Health Administration (OSHA).
Reproductive Toxicity:	Not available
Specific Target Organ Toxicity – Single Exposure:	Respiratory tract irritant
Specific Target Organ Toxicity – Repeated Exposure:	Not available
Aspiration Hazard:	Not available. Not expected to be of concern.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity:	Not available for Dyclonine hydrochloride Hydrochloric Acid – Aquatic LC50: 829 mg/L @96 hrs, estimated – fish
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	Sodium Chloride – Aquatic EC50: 340.7 mg/L @48 hrs – water flea
Persistence / Degradability:	Not available
Bioaccumulation / Accumulation:	Not available
Mobility in Environmental Media:	Not available
Other Adverse Effects:	Not available

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal:	Observe all Federal/Provincial/State and Local disposal regulations.
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SECTION 14: TRANSPORTATION INFORMATION

UN Number:	Not available
UN Proper Shipping Name:	Not available
Transport Hazard Classes:	Not available
Packing Group:	Not available
Environmental Hazards:	Not available
Special Precautions for User:	None

SECTION 15: REGULATORY INFORMATION

Regulatory Status:	This product is exempt from current WHMIS legislation as a drug product.
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SECTION 16: OTHER INFORMATION

Name of person or group that prepared SDS:	Septodont in conjunction with a third party consultant
Phone #:	519-623-4800
SDS Version#:	# 3; (replaces v.2 of July 11, 2016)

Information and statements contained in this document have been obtained from manufacturers, suppliers and recognized reference sources as provided to or obtained by Septodont.

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