

SAFETY DATA SHEET

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Version 3

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

Product name: Cook-Waite Zorcaine(TM/MC) (articaine hydrochloride 4% with 1:100,000 epinephrine as tartrate, injection)

Product code: 1164011

Supplier Carestream Health Canada, 8800 Dufferin Street, Suite 201, Vaughan, Ontario, L4K 0C5

For Emergency Health Information call: 800-424-9300

For other information contact: 800-328-2910

Product Use: Anesthetic (prescription drug). Restricted to professional users.

2. HAZARDS IDENTIFICATION

Classification

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label elements

Emergency Overview

Appearance No information available **Physical state** liquid **Odor** Odorless

Hazards not otherwise classified (HNOC)

- Not applicable

Other Information

Can cause local anesthesia (numbness in the exposed area).

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %	Trade Secret
Water 7732-18-5	7732-18-5	94-99	*

Methyl 4-methyl-3-[[[(1-oxo-2-(propylamino)propyl)amino]-2- thenoate monohydrochloride 23964-57-0	23964-57-0	1-5	*
Epinephrine tartrate 1234-55-5	1234-55-5	<1	*

*The exact percentages (concentrations) have been withheld as trade secrets.

4. FIRST AID MEASURES

First Aid Measures

General advice	If symptoms persist, call a physician. Show this material safety data sheet to the doctor in attendance.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention immediately if symptoms occur.
Skin contact	Wash off immediately with soap and plenty of water for at least 15 minutes while removing all contaminated clothing and shoes. Get medical attention immediately if symptoms occur. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes.
Inhalation	Move to fresh air. Get medical attention immediately if symptoms occur.
Ingestion	If swallowed, do not induce vomiting - seek medical advice. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Call a physician or Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed

Main Symptoms Can cause local anesthesia (numbness in the exposed area).

Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically. May cause sensitization of susceptible persons.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media

None.

Specific hazards arising from the chemical

Thermal decomposition can lead to release of irritating gases and vapors. May cause sensitization by inhalation and skin contact.

Hazardous Combustion Products

None.

Explosion Data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Use personal protective equipment. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation. Avoid breathing vapors or mists.

Environmental precautions

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

Methods for Containment Prevent further leakage or spillage if safe to do so. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up Cover liquid spill with sand, earth or other noncombustible absorbent material. Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Use only in area provided with appropriate exhaust ventilation. Avoid breathing vapors or mists. Avoid contact with skin, eyes and clothing. Wash thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical measures/Storage conditions Keep container tightly closed in a dry and well-ventilated place. Storage separately from incompatible materials.

Incompatible products Strong oxidizing agents.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

Chemical Name	ACGIH TLV	AIHA - Workplace Environmental Exposure Levels (WEELs) - TWAs	OSHA PEL	Advisory OEL
Sodium metabisulfite 7681-57-4	TWA: 5 mg/m ³		-	
Sodium hydroxide 1310-73-2	Ceiling: 2 mg/m ³		TWA: 2 mg/m ³	

Appropriate engineering controls

Engineering Measures Ensure adequate ventilation. Apply technical measures to comply with the occupational exposure limits. Showers. Eyewash stations.

Individual protection measures, such as personal protective equipment

Eye/Face Protection Safety glasses with top and side-shields. If splashes are likely to occur, wear:. Face-shield.

Skin and body protection Impervious gloves. Skin contact should be prevented through use of suitable protective clothing, gloves, and footwear, selected with regard of use conditions and exposure potential.

Respiratory protection None required under normal usage.

Hygiene measures Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL AND CHEMICAL PROPERTIES

Physical state	liquid	Odor	Odorless
Appearance	No information available	Odor Threshold	No information available
Color	colorless		

<u>Property</u>	<u>Values</u>	<u>Remarks/ • Method</u>
ph	4.0 - 4.5	
Melting point/range:		No information available
Boiling point/boiling range		No information available
Flash Point		Does not flash.
Evaporation rate		No information available
Flammability (solid, gas)		
upper flammability limit		
lower flammability limit		
Vapor pressure	24 hPa	No information available
Vapor density	0.6	No information available
Specific Gravity		No information available
Water Solubility	Soluble in water	No information available
Solubility in other solvents		No information available
Partition coefficient: n-octanol/water		No information available
Autoignition temperature		No information available
Decomposition temperature		No information available
Viscosity, kinematic		No information available
Viscosity, dynamic		No information available
Oxidizing Properties	No information available	
Explosive properties	No information available	

Other information	No information available
Softening point	
Molecular Weight	No information available
Density	No information available
Bulk Density VALUE	No information available

10. STABILITY AND REACTIVITY

Reactivity
Not applicable

Chemical stability
Stable under recommended storage conditions.

Possibility of hazardous reactions
None under normal processing.

Conditions to Avoid

None known.

Incompatible Materials

Strong oxidizing agents.

Hazardous Decomposition Products

None under normal use.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation	Expected to be a low hazard for recommended handling.
Eye contact	May cause eye irritation.
Skin contact	May be harmful in contact with skin. May be absorbed through the skin in harmful amounts. May cause sensitization by skin contact.
Ingestion	May be harmful if swallowed. Some asthmatics or sulfite-sensitive individuals may experience wheezing, chest tightness, stomach upset, hives, faintness, weakness and diarrhea.

Toxicology data for the components

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Water 7732-18-5	90,000 mg/kg (Rat)	-	-
Methyl 4-methyl-3-[[[1-oxo-2-(propylamino) propyl]amino]-2-thenoate monohydrochloride 23964-57-0	978 mg/kg (rat)	-	-
Sodium chloride 7647-14-5	3 g/kg (Rat) Oral LD50 Rat 3 g/kg (Source: IUCLID)	-	42 g/m ³ (Rat) 1 h Inhalation LC50 Rat >42 g/m ³ 1 h
Sodium metabisulfite 7681-57-4	1310 mg/kg (Rat) Oral LD50 Rat 1310 mg/kg (Source: JAPAN_GHS)	-	-
Sodium hydroxide 1310-73-2	140 mg/kg (rat)	1350 mg/kg (Rabbit) Dermal LD50 Rabbit 1350 mg/kg (Source: IUCLID)	-

Information on toxicological effects

Symptoms Can cause local anesthesia (numbness in the exposed area).

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Sensitization	May cause sensitization by skin contact.
mutagenic effects	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	No information available.
STOT - single exposure	No information available

STOT - repeated exposure No information available
Chronic toxicity Repeated contact may cause allergic reactions in very susceptible persons.
Aspiration Hazard No information available.

Numerical measures of toxicity - Product Information

Unknown acute toxicity
 The following values are calculated based on chapter 3.1 of the GHS document .
ATEmix (oral) 19560 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity

5.1% of the mixture consists of components(s) of unknown hazards to the aquatic environment

Chemical Name	Toxicity to algae	Toxicity to fish	Toxicity to microorganisms	Toxicity to daphnia and other aquatic invertebrates
Sodium chloride 7647-14-5		4747 - 7824: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 5560 - 6080: 96 h Lepomis macrochirus mg/L LC50 flow-through 6020 - 7070: 96 h Pimephales promelas mg/L LC50 static 6420 - 6700: 96 h Pimephales promelas mg/L LC50 static 12946: 96 h Lepomis macrochirus mg/L LC50 static 7050: 96 h Pimephales promelas mg/L LC50 semi-static		340.7 - 469.2: 48 h Daphnia magna mg/L EC50 Static 1000: 48 h Daphnia magna mg/L EC50
Sodium metabisulfite 7681-57-4	40: 96 h Desmodesmus subspicatus mg/L EC50 48: 72 h Desmodesmus subspicatus mg/L EC50	32: 96 h Lepomis macrochirus mg/L LC50 static		
Sodium hydroxide 1310-73-2		45.4: 96 h Oncorhynchus mykiss mg/L LC50 static		

Persistence and degradability
 No information available.

Bioaccumulation:
 No information available.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

Contaminated packaging Do not re-use empty containers. Dispose of in accordance with local regulations.

14. TRANSPORT INFORMATION

The information given below is provided to assist in documentation. It may supplement the information on the package. The package in your possession may carry a different version of the label depending on the date of manufacture. Depending on inner packaging quantities and packaging instructions, it may be subject to specific regulatory exceptions. Please consult the product packaging for further details.

<u>DOT</u>	Not regulated
<u>TDG</u>	Not regulated
<u>ICAO/IATA</u>	Not regulated
<u>IMDG/IMO</u>	Not regulated

For transportation information, go to: <http://ship.carestream.com>

15. REGULATORY INFORMATION

International Inventories

TSCA	Does not comply
DSL/NDSL	Does not comply
EINECS/ELINCS	Does not comply
ENCS	Does not comply
IECSC	Does not comply
KECL	Does not comply
PICCS	Does not comply
AICS	Does not comply
NZIoC	Does not comply

Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances
NZIoC - New Zealand Inventory of Chemicals

16. OTHER INFORMATION

Revision Date 2015-05-19
Revision Note (M)SDS sections updated

Disclaimer

The information provided on this MSDS 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 guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as 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 material or in any process, unless specified in the text