

SAFETY DATA SHEET

Issuing date 2014-10-01

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Version 1

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

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

Product code: 8942831

Supplier Carestream Health, Inc., 150 Verona Street, Rochester, New York 14608

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	*
Sodium chloride 7647-14-5	7647-14-5	<1	*
Sodium metabisulfite 7681-57-4	7681-57-4	<1	*
Sodium hydroxide 1310-73-2	1310-73-2	<1	*
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. Adverse effects may be more pronounced in those receiving medications to alter blood pressure, or people with cardiovascular disease or drug sensitivity or allergy. See package insert for more detailed information.

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	
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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 side-shields. If splashes are likely to occur, wear: Face-shield.
- Skin and body protection** Wear appropriate clothing if necessary. 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		
Property	Values	Remarks/ • Method	
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		No information available	
Molecular Weight		No information available	
Density VALUE		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 component(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.

Chemical Name	log Pow
Sodium metabisulfite 7681-57-4	-3.7

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

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.

This product contains one or more substances that are listed with the State of California as a hazardous waste.

Chemical Name	California Hazardous Waste Status
Sodium hydroxide 1310-73-2	Toxic Corrosive

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.

- DOT** Not regulated
- TDG** Not regulated
- ICAO/IATA** Not regulated
- IMDG/IMO** Not regulated

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

15. REGULATORY INFORMATION

This is a drug and is regulated under the FDA

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

U.S. Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute Health Hazard	Yes
Chronic Health Hazard	Yes
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

Clean Water Act

This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42):

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Sodium hydroxide	1000 lb			X

Clean Air Act, Section 112 Hazardous Air Pollutants (HAPs) (see 40 CFR 61)

This product does not contain any substances regulated as hazardous air pollutants (HAPS) under Section 112 of the Clean Air Act Amendments of 1990.

CERCLA

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302):

Chemical Name	Hazardous Substances RQs	Extremely Hazardous Substances RQs	SARA Product RQ
Sodium hydroxide	1000 lb		

TSCA

Chemical Name	U.S. - TSCA (Toxic Substances Control Act) - Section 8(a) - Chemical-Specific Reporting and Recordkeeping	
Sodium metabisulfite	PAIR: 01/26/1994	
Component	U.S. - TSCA (Toxic Substances Control Act) - Section 8(d) - 716.120(a) - Health and Safety Reporting - List of Substances	
Sodium metabisulfite 7681-57-4 (<1)	01/26/1994	

U.S. State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

Chemical Name	Massachusetts	New Jersey	Pennsylvania	Illinois	Rhode Island
Sodium metabisulfite	X	X	X		X
Sodium hydroxide	X	X	X		X

International Regulations

Mexico - Grade	No information available	
Chemical Name	Carcinogen Status	Exposure Limits
Sodium hydroxide		Mexico: Ceiling 2 mg/m ³

16. OTHER INFORMATION

NFPA	Health Hazard 1	Flammability 0	Instability 0
HMIS	Health Hazard 1	Flammability 0	Physical Hazard 0

Revision Date 2014-10-01
Revision Note (M)SDS sections updated

Disclaimer

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.

End of Safety Data Sheet