

# SAFETY DATA SHEET

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Version 1

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

**Product name:** Cook-Waite Marcaine® 0.5% with epinephrine 1:200,000 injection (as bitartrate)

**Product code:** 1852557

**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).

## 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	98-100	*

Sodium chloride 7647-14-5	7647-14-5	<1	*
Bupivacaine hydrochloride 18010-40-7	18010-40-7	<1	*
Sodium metabisulfite 7681-57-4	7681-57-4	<0.1	*

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

## 4. FIRST AID MEASURES

### First Aid Measures

<b>General advice</b>	If symptoms persist, call a physician. Show this material safety data sheet to the doctor in attendance.
<b>Eye contact</b>	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention immediately if symptoms occur.
<b>Skin contact</b>	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.
<b>Inhalation</b>	Move to fresh air. Get medical attention immediately if symptoms occur.
<b>Ingestion</b>	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. Do not breathe vapors or spray mist.

**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.

**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** This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

**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** Impervious gloves. Skin contact with the product must be prevented through the use of suitable protective clothing, gloves and footwear selected according to use condition 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

<b>Physical state</b>	liquid	<b>Odor</b>	Odorless
<b>Appearance</b>	No information available	<b>Odor Threshold</b>	No information available
<b>Color</b>	colorless		
<b>Property</b>	<b>Values</b>	<b>Remarks/ • Method</b>	
ph			
<b>Melting point/range:</b>	> 100 °C	No information available	
<b>Boiling point/boiling range</b>		No information available	
<b>Flash Point</b>		Does not flash.	
<b>Evaporation rate</b>		No information available	
<b>Flammability (solid, gas)</b>			
upper flammability limit			
lower flammability limit			
<b>Vapor pressure</b>	24 hPa	No information available	
<b>Vapor density</b>	0.6	No information available	
<b>Specific Gravity</b>		No information available	
<b>Water Solubility</b>	Soluble in water	No information available	
<b>Solubility in other solvents</b>		No information available	
<b>Partition coefficient: n-octanol/water</b>		No information available	
<b>Autoignition temperature</b>		No information available	
<b>Decomposition temperature</b>		No information available	
<b>Viscosity, kinematic</b>		No information available	
<b>Viscosity, dynamic</b>		No information available	
<b>Oxidizing Properties</b>	No information available		
<b>Explosive properties</b>	No information available		
<b>Other information</b>		No information available	
<b>Softening point</b>			
<b>Molecular Weight</b>		No information available	
<b>Density VALUE</b>		No information available	
<b>Bulk Density VALUE</b>		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**  
To avoid thermal decomposition, do not overheat. Protect from light.

**Incompatible Materials**  
Strong oxidizing agents.

**Hazardous Decomposition Products**

None under normal use.

**11. TOXICOLOGICAL INFORMATION**

**Information on likely routes of exposure**

**Product Information**

<b>Inhalation</b>	Expected to be a low hazard for recommended handling.
<b>Eye contact</b>	May cause eye irritation.
<b>Skin contact</b>	Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. May be absorbed through the skin in harmful amounts.
<b>Ingestion</b>	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 )	-	-
Sodium chloride 7647-14-5	3 g/kg ( Rat ) Oral LD50 Rat 3 g/kg (Source: IUCLID)	-	42 g/m <sup>3</sup> ( Rat ) 1 h Inhalation LC50 Rat >42 g/m <sup>3</sup> 1 h
Sodium metabisulfite 7681-57-4	1310 mg/kg ( Rat ) Oral LD50 Rat 1310 mg/kg (Source: JAPAN_GHS)	-	-

**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**

<b>Sensitization</b>	May cause sensitization by skin contact.
<b>mutagenic effects</b>	No information available.
<b>Carcinogenicity</b>	No information available.
<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available
<b>STOT - repeated exposure</b>	No information available
<b>Chronic toxicity</b>	Repeated contact may cause allergic reactions in very susceptible persons.
<b>Aspiration Hazard</b>	No information available.

**Numerical measures of toxicity - Product Information**

**Unknown acute toxicity**  
ATEmix (oral) >5000 mg/kg

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

1.66% 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

**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.

**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

<b>TSCA</b>	Does not comply
<b>DSL/NDSL</b>	Complies
<b>EINECS/ELINCS</b>	Complies
<b>ENCS</b>	Does not comply
<b>IECSC</b>	Does not comply
<b>KECL</b>	Does not comply
<b>PICCS</b>	Does not comply
<b>AICS</b>	Does not comply
<b>NZIoC</b>	Complies

### 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**

<b>Acute Health Hazard</b>	Yes
<b>Chronic Health Hazard</b>	Yes
<b>Fire Hazard</b>	No
<b>Sudden Release of Pressure Hazard</b>	No
<b>Reactive Hazard</b>	No

#### **Clean Water Act**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

#### **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, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

**TSCA**

<b>Chemical Name</b>	<b>U.S. - TSCA (Toxic Substances Control Act) - Section 8(a) - Chemical-Specific Reporting and Recordkeeping</b>	
Sodium metabisulfite	PAIR: 01/26/1994	
<b>Component</b>	<b>U.S. - TSCA (Toxic Substances Control Act) - Section 8(d) - 716.120(a) - Health and Safety Reporting - List of Substances</b>	
Sodium metabisulfite 7681-57-4 ( <0.1 )	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**

This product does not contain any substances regulated by state right-to-know regulations

**International Regulations**

**Mexico - Grade** No information available

**16. OTHER INFORMATION**

<b><u>NFPA</u></b>	<b>Health Hazard</b> 1	<b>Flammability</b> 0	<b>Instability</b> 0
<b><u>HMIS</u></b>	<b>Health Hazard</b> 1	<b>Flammability</b> 0	<b>Physical Hazard</b> 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**