SAFETY DATA SHEETS

This SDS packet was issued with item:

072218527

N/A



MATERIAL SAFETY DATA SHEET

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Issuing date 2012-05-16 **Revision Date** 2012-05-16 **Version** 2

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

Product name: COOK-WAITE MARCAINE HCI 0.5% Bupivacaine

Product code: 1089879

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).

HAZARDS IDENTIFICATION

Warning!

Emergency Overview

May be harmful if swallowed

Can cause local anesthesia (numbness in the exposed area)

Physical state liquid Odor Odorless Color colorless

HMIS Health Hazard - 1* Flammability - 0 Physical - 0
Hazard

Potential Health Effects

Eyes No hazard from product as supplied. Contact with eyes may cause irritation.

Skin Non-irritating during normal use. This material has a low potential to cause allergic skin

reactions, however, cases of human skin sensitization have been reported.

Inhalation Not an expected route of exposure.

Ingestion May be harmful if swallowed. Some asthmatics or sulfite-sensitive individuals may

experience wheezing, chest tightness, stomach upset, hives, faintness, weakness and

diarrhea.

Chronic Effects

Chronic toxicity Repeated contact may cause allergic reactions in very susceptible persons.

Aggravated Medical Conditions Skin disorders.

Environmental hazard See Section 12 for additional Ecological Information.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<u>Hazardous</u>

Chemical Name	CAS-No	Weight %
Bupivacaine hydrochloride	18010-40-7	<1
Sodium metabisulfite	7681-57-4	<0.1

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Non-Hazardous

Chemical Name	CAS-No	Weight %
Water	7732-18-5	98-100

4. 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 contactWash 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.

Notes to physician Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Flammable Properties None known.

Flash point: Does not flash

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Unsuitable Extinguishing Media None.

Hazardous Combustion Products 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.

NFPA Health Hazard - 1 Flammability - 0 Stability - 0

ACCIDENTAL RELEASE MEASURES

Personal precautions Use personal protective equipment. Evacuate personnel to safe areas. Keep people away

from and upwind of spill/leak.

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.

Other information See Section 12 for additional information.

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HANDLING AND STORAGE

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.

Technical measures/Storage

conditions

Keep container tightly closed in a dry and well-ventilated place. Storage separately from

incompatible materials.

EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines This product does not contain any hazardous materials with occupational exposure limits

established by the region specific regulatory bodies.

Occupational Exposure Controls

Engineering Measures Ensure adequate ventilation. Apply technical measures to comply with the occupational

exposure limits.

Personal Protective Equipment

General Information These recommendations apply to the product as supplied.

Respiratory protection None required under normal usage.

Eye/Face Protection Safety glasses with side-shields.

Skin and body protection Wear appropriate clothing if necessary.

Hand Protection Impervious gloves.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state liquid Odor Odorless
ph No information available Color colorless

Flash point: Does not flash

Boiling point/boiling range No information available

Autoignition temperature: No information available

Vapor Pressure 24 hPa Vapor density 0.6

Density No information available

Volatile organic compounds (VOC) content 97

Water Solubility Soluble in water Melting point/range: > 100 °C

Specific Gravity No information available **Bulk Density:** No information available

10. STABILITY AND REACTIVITY

Stability Stable under normal conditions.

Incompatible products None.

Conditions to Avoid None known.

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Hazardous Decomposition Products None under normal use.

Hazardous Polymerization Hazardous polymerization does not occur.

11. TOXICOLOGICAL INFORMATION

Acute toxicity - Product Information

SkinNon-irritating during normal use. This material has a low potential to cause allergic

skin reactions, however, cases of human skin sensitization have been reported.

EyesNo hazard from product as supplied. Contact with eyes may cause irritation.

Inhalation Not an expected route of exposure.

Ingestion May be harmful if swallowed. Some asthmatics or sulfite-sensitive individuals may

experience wheezing, chest tightness, stomach upset, hives, faintness, weakness

and diarrhea.

Acute toxicity - Component Information

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Water	90,000 mg/kg (Rat)		
Sodium metabisulfite	1131 mg/kg (Rat)	2 g/kg (Rat)	

Subchronic toxicity No information available

Chronic toxicity Repeated contact may cause allergic reactions in very susceptible persons.

Carcinogenicity Contains no ingredient listed as a carcinogen.

Target Organ Effects None known.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects The environmental impact of this product has not been fully investigated.

Component Information

Chemical Name	Toxicity to algae	Toxicity to fish	Toxicity to daphnia and other aquatic invertebrates
Sodium metabisulfite	48 mg/L EC50 72 h (Desmodesmus subspicatus) 40 mg/L EC50 96 h (Desmodesmus subspicatus)	LC50= 32 mg/L Lepomis macrochirus 96 h	EC50 = 89 mg/L 24 h (Daphnia magna Straus)

Persistence and degradability No information available

Bioaccumulation: - No information available

Mobility - No information available

Chemical Name log Pow	Chemical Name	log Pow
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Sodium metabisulfite	-3.7

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 Observe all labeled safeguards until container is cleaned, reconditioned or destroyed.

Empty containers should be taken to an approved waste handling site for recycling or

disposal.

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.carestreamhealth.com.

15. REGULATORY INFORMATION

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all the information required by the CPR.

WHMIS Hazard Class

D2B Toxic materials



International Inventories

TSCA Does not comply
DSL/NDSL Complies
EINECS/ELINCS Complies

ENCS Does not comply
IECSC Does not comply
KECL Does not comply
PICCS Does not comply

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AICS Does not comply NZIOC 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

16. OTHER INFORMATION

Disclaimer for Label

The data below reflects current legislative requirements whereas the product in your possession may carry a different version of the label depending on the date of manufacture.



Warning!

- Contains:

Hazardous Components

Chemical Name	CAS-No	Weight %
Bupivacaine hydrochloride	18010-40-7	<1
Sodium metabisulfite	7681-57-4	<0.1

May be harmful if swallowed. Can cause local anesthesia (numbness in the exposed area).

Avoid contact with skin, eyes and clothing. Avoid breathing vapors or mists. Ensure adequate ventilation. Wash thoroughly after handling.

Additional information is given in the Material Safety Data Sheet.

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



SAFETY DATA SHEET

Issuing date 2015-05-19 Revision Date 2015-05-19 Version 4

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

Product name: COOK-WAITE MARCAINE HCI 0.5% Bupivacaine

Product code: 1089879

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).

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	*
Bupivacaine hydrochloride 18010-40-7	18010-40-7	<1	*

Sodium metabisulfite	7681-57-4	<0.1	*
7681-57-4			

^{*}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

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 top and side-shields. If splashes are likely to occur, wear:. Face-shield.

Skin and body protection Impervious gloves.

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

Appearance No information available Odor Odorless

Color colorless Odor Threshold No information available

Property Values Remarks/ • Method

ph

Melting point/range:> 100 °CNo information availableBoiling point/boiling rangeNo information available

Flash Point Does not flash.

Evaporation rateNo 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 No information available **Specific Gravity** No information available **Water Solubility** Soluble in water Solubility in other solvents No information available No information available Partition coefficient: n-octanol/water **Autoignition temperature**

Autoignition temperatureNo information availableDecomposition temperatureNo information availableViscosity, kinematicNo information availableViscosity, dynamicNo information available

Oxidizing PropertiesNo information availableExplosive propertiesNo information available

<u>Other information</u> No information available

Softening pointNo information availableMolecular WeightNo information availableDensityNo information availableBulk Density VALUENo 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

Inhalation Expected to be a low hazard for recommended handling.

Eye contact May cause eye irritation.

Skin contact Repeated or prolonged skin contact may cause allergic reactions with susceptible persons.

May be absorbed through the skin in harmful amounts.

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)	-	-
Sodium chloride 7647-14-5	3 g/kg(Rat) Oral LD50 Rat 3 g/kg (Source: IUCLID)	-	42 g/m³ (Rat) 1 h Inhalation LC50 Rat >42 g/m³ 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

Sensitization May cause sensitization by skin contact.

mutagenic effectsNo information available.CarcinogenicityNo information available.Reproductive toxicityNo information available.STOT - single exposureNo information availableSTOT - repeated exposureNo 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

ATEmix (oral) >5000 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity

1.66% of the mixture consists of components(s) of unknown hazards to the aquatic environment

Chemical Name	Toxicity to algae	Toxicity to fish	Toxicity to	Toxicity to daphnia and
			microorganisms	other aquatic invertebrates

Sodium chloride	4747 - 7824: 96 h	340.7 - 469.2: 48 h Daphnia
7647-14-5	Oncorhynchus mykiss mg/L	magna mg/L EC50 Static
	LC50 flow-through 5560 -	1000: 48 h Daphnia magna
	6080: 96 h Lepomis	mg/L EC50
	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	

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 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

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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

International Inventories

TSCA Does not comply
DSL/NDSL Complies
EINECS/ELINCS Complies

ENCS
Does not comply
IECSC
Does not comply
KECL
Does not comply
PICCS
Does not comply
Does not comply
AICS
Does not comply
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

16. OTHER INFORMATION

Revision Date 2015-05-19

Revision Note (M)SDS sections updated

Disclaimer

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