

SAFETY DATA SHEETS

This SDS packet was issued with item:

072218527

N/A

MATERIAL SAFETY DATA SHEET

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 HCl 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

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

Hazardous

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

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 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. |
| 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

6. 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. |

7. 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. |

8. 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. |
| <u>Occupational Exposure Controls</u> | |
| Engineering Measures | Ensure adequate ventilation. Apply technical measures to comply with the occupational exposure limits. |
| <u>Personal Protective Equipment</u> | |
| 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 | Autoignition temperature: No information available |
| Boiling point/boiling range 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. |

Hazardous Decomposition Products None under normal use.

Hazardous Polymerization Hazardous polymerization does not occur.

11. TOXICOLOGICAL INFORMATION

Acute toxicity - Product Information

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.

Eyes No 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 |
|---------------|---------|
|---------------|---------|

| | |
|----------------------|------|
| 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

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 HCl 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 | 7681-57-4 | <0.1 | * |
|-----------------------------------|-----------|------|---|

*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. 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 | Odor | Odorless |
| Appearance | No information available | Odor Threshold | No information available |
| Color | colorless | | |
| Property | Values | Remarks/ • Method | |
| ph | | | |
| Melting point/range: | > 100 °C | 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

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/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) | - | - |

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
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 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 regulatedFor 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 |
| 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 |
|------------------------------|

| | |
|---------------|-------------------------|
| 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