

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 Lidocaine HCl 2% and Epinephrine 1:100,000 Injection

Product code: 1559889

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 | 95-99 | * |

| | | | |
|--|-----------|---------|---|
| Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)- 137-58-6 | 137-58-6 | 1-5 | * |
| Sodium chloride 7647-14-5 | 7647-14-5 | 0.1-1.0 | * |
| Sodium bisulfate 7681-38-1 | 7681-38-1 | <0.1 | * |
| 1,2-Benzenediol, 4-[1-hydroxy-2-(methylamino)ethyl] 51-43-4 | 51-43-4 | < 0.01 | * |

*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. Do not breathe dust/fume/gas/mist/vapors/spray. |
| Eye contact | Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. If eye irritation persists, consult a specialist. |
| Skin contact | Immediate medical attention is not required. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. If symptoms persist, call a physician. |
| Inhalation | Move to fresh air. Consult a physician. Immediate medical attention is not required. If symptoms persist, call a physician. |
| Ingestion | Rinse mouth. Drink plenty of water. If symptoms persist, call a physician. Do NOT induce vomiting. Clean mouth with water. Never give anything by mouth to an unconscious person. |
| Protection of First-aiders | Use personal protective equipment. |

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.

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

No information available.

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 entry into waterways, sewers, basements or confined areas. Do not flush into surface water or sanitary sewer system. Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.

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 Avoid contact with skin, eyes and clothing. Wear personal protective equipment. Prevent the formation of vapors, mists and aerosols. Do not eat, drink or smoke when using this product. Use only in area provided with appropriate exhaust ventilation. Avoid breathing vapors or mists.

Conditions for safe storage, including any incompatibilities

Technical measures/Storage conditions Keep away from direct sunlight. Keep container tightly closed in a dry and well-ventilated place.

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 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 | When using, do not eat, drink or smoke. Provide regular cleaning of equipment, work area and clothing. |

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 | 3.3 - 5.5 | | |
| Melting point/range: | | No information available | |
| Boiling point/boiling range | > 100 °C | No information available | |
| Flash Point | | No information available. | |
| 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. |
| Ingestion | May be harmful if swallowed. |

Toxicology data for the components

| Chemical Name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|--|--|-------------|---|
| Water 7732-18-5 | 90,000 mg/kg (Rat) | - | - |
| Acetamide, 2-(diethylamino)-N-(2,6-dimethylphe nyl)- 137-58-6 | Oral LD50 Mouse 220 mg/kg (Source: NZ_CCID) | - | - |
| 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 bisulfate 7681-38-1 | 2490 mg/kg (Rat) Oral LD50 Rat 2490 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 | No information available. |
| 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 | No known effect. Avoid repeated exposure. |
| Aspiration Hazard | No information available. |

Numerical measures of toxicity - Product Information

Unknown acute toxicity
ATEmix (oral)

>5000 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity

2.005% 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 bisulfate 7681-38-1 | | | | 190: 48 h Daphnia magna mg/L EC50 |

Persistence and degradability

No information available.

Bioaccumulation:

No information available.

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.

| Chemical Name | RCRA | RCRA - Basis for Listing | RCRA - D Series Wastes | RCRA - U Series Wastes |
|--|------|--------------------------|------------------------|------------------------|
| 1,2-Benzenediol, 4-[1-hydroxy-2-(methylamino)ethyl] 51-43-4 | P042 | | | |

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

"Does not comply" indicates a component is either not on the public inventory or is subject to exemption requirements. If additional information is needed contact Carestream Health.

International Inventories

| | |
|----------------------|-----------------|
| TSCA | Complies |
| DSL/NDSL | Complies |
| EINECS/ELINCS | Complies |
| ENCS | Complies |
| IECSC | Does not comply |
| KECL | Does not comply |
| PICCS | Complies |
| AICS | Complies |
| 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

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 | No |
| Fire Hazard | No |
| Sudden Release of Pressure Hazard | No |
| Reactive Hazard | 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, 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 |
|---|--------------------------|------------------------------------|-----------------|
| 1,2-Benzenediol, 4-[1-hydroxy-2-(methylamino)ethyl] | 1000 lb | | |

TSCA

This product does not contain any chemicals regulated under TSCA Section 4, Section 5(a), Section 8(a) or Section 8(d).

U.S. State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

International Regulations

Mexico - Grade No information available

16. OTHER INFORMATION

| | | | |
|--------------------|------------------------|-----------------------|--------------------------|
| <u>NFPA</u> | Health Hazard 1 | Flammability 0 | Instability 0 |
| <u>HMIS</u> | 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