SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME
BUPIVACAINE HYDROCHLORIDE, USP (Monohydrate)

PRODUCT CODE
0524

SUPPLIER
MEDISCA Inc.
Tel.: 1.800.932.1039 | Fax.: 1.855.850.5855
661 Route 3, Unit C, Plattsburgh, NY, 12901
3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118
6641 N. Belt Line Road, Suite 130, Irving, TX, 75063

MEDISCA Pharmaceutique Inc.
Tel.: 1.800.665.6334 | Fax.: 514.338.1693
4509 Rue Dobrin, St. Laurent, QC, H4R 2L8
21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2

MEDISCA Australia Pty Ltd
Tel.: 1.300.786.392 | Fax.: 61.2.9700.9047
Unit 7, Heritage Business Park
5-9 Ricketty Street, Mascot, NSW 2020

EMERGENCY PHONE
CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300
NSW Poisons Information Centre: 131 126
National Chemical Emergency Centre 44(0)1235239670

USES
Local anesthetic

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION
Acute Toxicity - Oral (Category 2)
Specific Target Organ Toxicity - Single Exposure (Category 3) - Narcotic Effect
Acute Aquatic Toxicity (Category 3)

PICTOGRAM

SIGNAL WORD
Danger

HAZARD STATEMENT(S)
Fatal if swallowed.
Fatal if in contact with skin.
Fatal if inhaled.
Avoid contact with skin and eyes.
May damage fertility or the unborn child.
May cause drowsiness or dizziness.
May cause allergic reaction
Harmful to aquatic life.
May cause long lasting harmful effects to aquatic life.

ADVERSE PHYSICOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS
Not Applicable
PRECAUTIONARY STATEMENT(S)

Prevention
- Wash thoroughly after handling.
- Do not eat, drink or smoke when using this product.
- Obtain special instructions before use.
- Do not handle until all safety precautions have been read and understood.
- Wear protective gloves, protective clothing, eye protection, face protection.
- Avoid breathing dust/fume/gas/mist/vapors/spray.
- Use only outdoors or in a well-ventilated area.
- Avoid release to the environment.

Response
- IF SWALLOWED: Immediately call a poison center or medical professional; Rinse mouth.
- IF EXPOSED OR CONCERNED: Get medical advice/attention.
- IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell.

Storage
- Store in a well ventilated place.
- Keep container tightly closed.
- Store locked up.

Disposal
- Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION
- Health Hazard: 3
- Flammability: 1
- Reactivity: 0
- Personal Protection: G

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME: (+/-)-1-Butyl-2',6'-pipecoloxyloixidide monohydrochloride, monohydrate

BOTANICAL NAME: Not applicable

SYNONYM: Not applicable

CHEMICAL FORMULA: C₃₈H₅₈N₂O.HCl.H₂O

CAS NUMBER: 14252-80-3

ALTERNATE CAS NUMBER: 73360-54-0

MOLECULAR WEIGHT: 342.9079

COMPOSITION

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>EC NUMBER</th>
<th>% BY WEIGHT</th>
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</thead>
<tbody>
<tr>
<td>BUPIVACAINE HCl (Monohydrate)</td>
<td>14252-80-3</td>
<td>627-065-3</td>
<td>100</td>
</tr>
</tbody>
</table>

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

NOTES
- Chemical family: Piperidine derivative; amino amide.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT
- Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT
- Wash with soap & water for 15 minutes. Cover the irritated skin with an emollient. If irritation persists seek medical aid.

IF SWALLOWED
- Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED
- Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

SYMPTOMS AND EFFECTS
- Not expected to present a significant hazard under anticipated conditions of normal use.
SAFETY DATA SHEET

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL
Emits toxic and corrosive fumes of CO, CO₂, NOₓ, HCl and unburnt organic and degradation products.

FLAMMABLE PROPERTIES
May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS
Under fire conditions, hazardous fumes will be present.

SUITEABLE & UNSUITABLE EXTINGUISHING MEDIA
Small fire: dry chemical, CO₂ or water spray. Large fire: dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS
Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS
Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT
On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE
Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

REFERENCE TO OTHER SECTIONS
See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING
Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling.

CONDITIONS FOR SAFE STORAGE
Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination. Preserve in well-closed containers. Protect from light. Ground all equipment containing material.

STORAGE CONDITIONS
Store in original container, tightly sealed, protected from direct sunlight and moisture. Preserve in well-closed containers. Protect from light.

SPECIFIC END USE(S)
See Section 1

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: BUPIVACAINE HCl (Monohydrate)  CAS #: 14252-80-3

<table>
<thead>
<tr>
<th>Country</th>
<th>Limit value-8 hours</th>
<th>Limit value-Short Term</th>
<th>IDLH</th>
<th>REL</th>
<th>Advisory</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ppm</td>
<td>mg/m³</td>
<td>ppm</td>
<td>mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OSHA</td>
<td>USA</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/A</td>
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</table>

Last Revision: 02/2020
SAFETY DATA SHEET

ACGIH USA N/L N/L N/L N/L N/L N/L N/A N/A
ACGIH N/A N/L N/L N/L N/L N/L N/L N/L
ACGIH N/A N/L N/L N/L N/L N/L N/L N/L
ACGIH UK N/L N/L N/L N/L N/L N/L N/A N/A
GMP N/L N/L N/L N/L N/L N/L N/A N/A
HSE UK N/L N/L N/L N/L N/L N/L N/A N/A
HSE UK N/L N/L N/L N/L N/L N/L N/L N/L
HSIS N/A N/L N/L N/L N/L N/L N/A N/A
HSIS N/A N/L N/L N/L N/L N/L N/L N/L
N/LSAFETY DATA SHEET

N/L = Not listed ; N/A = Not Available
PELs are 8-hour TWAs = Limit value - Eight hours
Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES
Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT
Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. Skin: Wear appropriate gloves to prevent skin exposure. Clothing: Wear appropriate protective clothing to minimize contact with skin. Respirators: Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. Thermal Hazards: For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS
Adequate mechanical ventilation. Fume hood, eye wash station, and safety shower.

NOTES
USP: ELV, industrial:
TWA: 0.05 mg/m³
STEL: 0.5 mg/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE
Solid

DESCRIPTION
White, odorless, crystalline powder.

SOLUBILITY
Freely soluble in water and in alcohol; slightly soluble in chloroform and in acetone.

ODOR
Odorless

FLAMMABILITY
May be combustible at high temperature

AUTO-IGNITION TEMPERATURE
Not available

BOILING POINT
423.4°C, 794.12°F

DECOMPOSITION TEMPERATURE
(248 - 259)°C, (478.4-498.2)°F

EVAPORATION RATE
Not available

EXPLOSIVE LIMIT
Not available

FLASH POINT
209 °C, 408.2 °F

log P (OCTANOL-WATER)
2.59 (20°C)

LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)
Not available

MELTING/FREEZING POINT
(248 - 259)°C, (478.4-498.2)°F (decomposes)

ODOR THRESHOLD
Not available

OXIDIZING PROPERTY
Not available

pH
4.5 - 6.0 (1%)

RELATIVE DENSITY (WATER = 1)
Not available

SPECIFIC GRAVITY
1.03 - 1.04

UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)
Not available

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BUPIVACAINE HYDROCHLORIDE, USP (Monohydrate)
SAFETY DATA SHEET

VAPOR DENSITY (AIR = 1) Not available VAPOR PRESSURE Not available VISCOSITY Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY Not established
CHEMICAL STABILITY Stable under recommended storage conditions
INCOMPATIBLE MATERIALS Strong oxidants, Strong acids, Methyl vinyl ether, Strong bases, Bases, Zinc.
HAZARDOUS DECOMPOSITION PRODUCTS Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride, unburnt organic degradation products and other gases may occur
HAZARDOUS POLYMERIZATION Will not occur
POSSIBILITY OF HAZARDOUS REACTION Not established
CONDITIONS TO AVOID Moisture, sunlight and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY Oral: Rat: LD50: (mg/kg): 18
Dermal: Rabbit LD50: (mg/kg): 1100 mg/kg
Inhalation: Rat: LC50: (mg/L/4hr): Not available

SKIN CORROSION/IRRITATION Due to lack of data the classification is not possible.
SERIOUS EYE DAMAGE/EYE IRRITATION Due to lack of data the classification is not possible.
RESPIRATORY SENSITIZATION Due to lack of data the classification is not possible.
By analogy to other local anesthetics, allergic reactions are possible with cross-sensitivity with amide-type anesthetics.
SKIN SENSITIZATION Due to lack of data the classification is not possible.
By analogy to other local anesthetics, allergic reactions are possible with cross-sensitivity with amide-type anesthetics.
GERM CELL MUTAGENICITY Due to lack of data the classification is not possible.
CARCINOGENICITY OSHA BUPIVACAINE HCI (Monohydrate) is not listed.
NTP BUPIVACAINE HCI (Monohydrate) is not listed.
IARC BUPIVACAINE HCI (Monohydrate) has not been evaluated.
California Proposition 65 This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

ADDITIONAL CARCINOGENICITY INFORMATION Due to lack of data the classification is not possible.

REPRODUCTIVE TOXICITY Based on available data, the classification criteria are not met.
Decreased pup survival in rats and embryocidal effect in rabbits have been observed when bupivacaine hydrochloride was administered to these species in doses comparable to nine and five times, respectively, the maximum recommended daily human dose (400mg)

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE Narcotic Effect
**SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE**

Due to lack of data the classification is not possible.

**ASPIRATION HAZARDS**

Based on available data, the classification criteria are not met.

**SIGNS AND SYMPTOMS OF EXPOSURE**

Symptoms related to the physical, chemical, and toxicological characteristics:

- Dizziness.
- Nervousness.
- Restlessness.
- Nausea.
- Vomiting.
- Blurred vision.
- Burning or tingling sensations.
- Tremor.
- Drowsiness.
- Disorientation.
- Difficulty breathing.

Delayed and immediate effects of exposure:

- Low blood pressure.
- Slow heartbeat.
- Irregular heartbeat.
- Ringing in ears.
- Seizures.
- Unconsciousness.
- Cardiac arrest.
- Coma.
- Death.

Cross sensitivity:

Persons sensitive to one amide-type local anesthetic may be sensitive to this material also.

Medical conditions aggravated by exposure:

- Heart problems.
- Impaired liver function.

Bupivacaine appears to be more cardiotoxic than other local anaesthetics. Cardiac arrest due to bupivacaine can be resistant to electrical defibrillation and a successful outcome may require prolonged resuscitative efforts.

**POTENTIAL HEALTH EFFECTS**

<table>
<thead>
<tr>
<th>Mode of Exposure</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>Fatal if inhaled. Causes respiratory tract irritation.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Fatal if swallowed.</td>
</tr>
<tr>
<td>Skin</td>
<td>Fatal if absorbed through skin. Causes skin irritation</td>
</tr>
<tr>
<td>Eyes</td>
<td>Causes eye irritation.</td>
</tr>
</tbody>
</table>

**SECTION 12: ECOLOGICAL INFORMATION**

**TOXICITY**

- EC50: 48 Hr: Crustacea: (mg/L): 39
- LC50: 96 Hr: Fish: (mg/L): Not available
- EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

**PERSISTENCE AND DEGRADABILITY**

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise. The products of degradation are more toxic.

**BIOACCUMULATIVE POTENTIAL**

Freely soluble in water

**MOBILITY IN SOIL**

Moderate: LogPow: 2.59 (20°C)

**OTHER ADVERSE EFFECTS**

This product is not intended to be released into the environment

**SECTION 13: DISPOSAL CONSIDERATIONS**

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

**SECTION 14: TRANSPORT INFORMATION**

UN PROPER SHIPPING NAME: TOXIC SOLID, ORGANIC, N.O.S.

UN NUMBER: 2811

CLASS: 6.1

PACKING GROUP: II
### Australia

**HAZCHEM**

| 2X |

### EU

**Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code**

- Not Listed

### Environmental Hazards

- Not available

### Special Shipping Information

- Not applicable

### Section 15: Regulatory Information

#### United States Regulations

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>CERCLA 40 CFR Part 302.4</th>
<th>SARA (Title III) 40 CFR Part 372.65</th>
<th>EPA 40 CFR Part 355 Appendix A</th>
<th>Appendix B</th>
<th>Pennsylvania</th>
<th>Right-to-know New Jersey</th>
<th>Massachusetts</th>
<th>California Prop 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>BUPIVACAINE HCl, 14252-80-3</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
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</tbody>
</table>

N/L = Not Listed; X = Listed

#### Australian Regulations

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>Poisons and Therapeutic Goods Regulation</th>
<th>Therapeutic Goods Act</th>
<th>Code of Practices - Illicit Drug Precursors</th>
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<tbody>
<tr>
<td>BUPIVACAINE HCl, 14252-80-3</td>
<td>N/L</td>
<td>Listed as Schedule 4*</td>
<td>N/L</td>
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</table>

N/L = Not Listed

#### EU Regulations

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<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
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</tbody>
</table>

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

**NOTES**

*Listed as the base

### Section 16: Other Information

#### References

Available upon request

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BUPIVACAINE HYDROCHLORIDE, USP (Monohydrate)  
Page 7 of 8
ABBREVIATIONS AND ACRONYMS


LAST REVISION

02/2020

SUPERSEDES

09/2016

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.