SAFETY DATA SHEET

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

CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300
NSW Poisons Information Centre: 131 126

USE
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
Danger

SIGNAL WORD

HAZARD STATEMENT(S)
Fatal if swallowed.
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.

AUSTRALIA-ONLY HAZARDS
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.
SAFETY DATA SHEET

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>(+/-)-1-Butyl-2',6'-pипецолохилдиле моногидрохлорид, моногидрат</th>
</tr>
</thead>
<tbody>
<tr>
<td>BOTANICAL NAME</td>
<td>Not applicable</td>
</tr>
<tr>
<td>SYNONYM</td>
<td></td>
</tr>
<tr>
<td>CHEMICAL FORMULA</td>
<td>C₁₈H₂₈N₂O.HCl.H₂O</td>
</tr>
<tr>
<td>CAS NUMBER</td>
<td>14252-80-3</td>
</tr>
<tr>
<td>ALTERNATE CAS NUMBER</td>
<td>73360-54-0</td>
</tr>
<tr>
<td>MOLECULAR WEIGHT</td>
<td>342.9079</td>
</tr>
<tr>
<td>COMPOSITION</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>NOTES</td>
<td>Chemical family: Piperidine derivative; amino amide.</td>
</tr>
</tbody>
</table>

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. 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.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL: Not applicable

FLAMMABLE PROPERTIES: May be combustible at high temperature

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

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.
SAFETY DATA SHEET

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS
Wear respiratory protection. 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.

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.

STORAGE CONDITIONS
Store in original container, tightly sealed container, protected from direct sunlight, in a dry and well-ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. Preserve in well-closed containers. Protect from light.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: BUPIVACAINE HYDROCHLORIDE CAS #: 14252-80-3

<table>
<thead>
<tr>
<th></th>
<th>TWA</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA PEL</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>NIOSH</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
</tr>
<tr>
<td>AIHA WEEL</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Safe Work Australia HSIS</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>HSE</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

N/L = Not Listed

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.

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

NOTES
USP ELV, industrial use:
- TWA: 0.05 mg/m³
- STEL: 0.5 mg/m³
### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>PROPERTY</th>
<th>VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PHYSICAL STATE</strong></td>
<td>Solid</td>
</tr>
<tr>
<td><strong>DESCRIPTION</strong></td>
<td>White, odorless, crystalline powder.</td>
</tr>
<tr>
<td><strong>SOLUBILITY</strong></td>
<td>Freely soluble in water and in alcohol; slightly soluble in chloroform and in acetone.</td>
</tr>
<tr>
<td><strong>ODOR</strong></td>
<td>Odorless</td>
</tr>
<tr>
<td><strong>FLAMMABILITY</strong></td>
<td>May be combustible at high temperature</td>
</tr>
<tr>
<td><strong>ODOR THRESHOLD</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>BOILING POINT</strong></td>
<td>423.4°C, 794.12°F</td>
</tr>
<tr>
<td><strong>FREEZING POINT</strong></td>
<td>(248 - 259)°C, (478.4-498.2)°F</td>
</tr>
<tr>
<td><strong>SPECIFIC GRAVITY</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>VAPOR DENSITY (AIR = 1)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>AUTO-IGNITION TEMPERATURE</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>DECOMPOSITION TEMPERATURE</strong></td>
<td>(248 - 259)°C, (478.4-498.2)°F</td>
</tr>
<tr>
<td><strong>MELTING POINT</strong></td>
<td>(248 - 259)°C, (478.4-498.2)°F (decomposes)</td>
</tr>
<tr>
<td><strong>FLASH POINT</strong></td>
<td>209 °C, 408.2 °F</td>
</tr>
<tr>
<td><strong>EXPLOSIVE LIMIT</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>VAPOR PRESSURE</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>RELATIVE DENSITY (WATER = 1)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>LOG P (OCTANOL-WATER)</strong></td>
<td>2.59 (20°C)</td>
</tr>
</tbody>
</table>

### SECTION 10: STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>PROPERTY</th>
<th>VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REACTIVITY</strong></td>
<td>Not established</td>
</tr>
<tr>
<td><strong>STABILITY</strong></td>
<td>Stable under recommended storage conditions</td>
</tr>
<tr>
<td><strong>MATERIALS TO AVOID</strong></td>
<td>Strong oxidants, Strong acids, Methyl vinyl ether, Strong bases, Bases, Zinc.</td>
</tr>
<tr>
<td><strong>HAZARDOUS DECOMPOSITION PRODUCTS</strong></td>
<td>Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur</td>
</tr>
<tr>
<td><strong>HAZARDOUS POLYMERIZATION</strong></td>
<td>Will not occur</td>
</tr>
<tr>
<td><strong>POSSIBILITY OF HAZARDOUS REACTION</strong></td>
<td>Not established</td>
</tr>
<tr>
<td><strong>CONDITIONS TO AVOID</strong></td>
<td>Moisture, sunlight and extreme temperatures</td>
</tr>
</tbody>
</table>

### SECTION 11: TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>PROPERTY</th>
<th>VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ACUTE TOXICITY</strong></td>
<td>Oral: Rat: LD50: (mg/kg): 18</td>
</tr>
<tr>
<td></td>
<td>Dermat: Rabbit LD50: (mg/kg): Not available</td>
</tr>
<tr>
<td></td>
<td>Inhalation: Rat: LD50: (mg/L/4hr): Not available</td>
</tr>
<tr>
<td><strong>SKIN CORROSION/IRRITATION</strong></td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

SERIOUS EYE DAMAGE/EYE IRRITATION
Due to lack of data the classification is not possible.

RESPIRATORY OR 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 HCl (Monohydrate) is not listed.
- NTP: BUPIVACAINE HCl (Monohydrate) is not listed.
- IARC: BUPIVACAINE HCl (Monohydrate) has not been evaluated.
- California: 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:

Delayed and immediate effects of exposure:

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
- Inhalation: Fatal if inhaled. Causes respiratory tract irritation.
- Ingestion: Fatal if swallowed.
- Skin: Fatal if absorbed through skin. Causes skin irritation
- Eyes: Causes eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY
- EC50: 48 Hr: Crustacea: (mg/L): 39
- LC50: 96 Hr: Fish: (mg/L): Not available
- IC50: 72 Hr: Algae: (mg/L): Not available

PERSISTENCE AND DEGRADABILITY
Not available

BIOACCUMULATIVE POTENTIAL
Moderate: LogPow: 2.59 (20°C)
MOBILITY IN SOIL
Freely soluble in water

OTHER ADVERSE EFFECTS
Not available
This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS

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

SECTION 14: TRANSPORT INFORMATION

UNITED STATES & CANADA
UN PROPER SHIPPING NAME
TOXIC SOLID, ORGANIC, N.O.S.
UN NUMBER
2811
CLASS
6.1
PACKING GROUP
II

AUSTRALIA
UN PROPER SHIPPING NAME
TOXIC SOLID, ORGANIC, N.O.S.
UN NUMBER
2811
CLASS
6.1
PACKING GROUP
II
HAZCHEM
2X
ENVIROMENTAL HAZARDS
Not available
SPECIAL SHIPPING INFORMATION
Not applicable

SECTION 15: REGULATORY INFORMATION

<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
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</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>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
</tr>
</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>
</tr>
</thead>
<tbody>
<tr>
<td>BUPIVACAINE HCl, 14252-80-3</td>
<td>N/L</td>
<td>Listed as Schedule 4*</td>
<td>N/L</td>
</tr>
</tbody>
</table>

NOTES
*Listed as the base
SECTION 16: OTHER INFORMATION

REFERENCES
Available upon request

ABBREVIATIONS AND ACRONYMS
CAS – Chemical Abstract Service; GHS – Global Harmonized System; OSHA PEL – Occupational Safety & Health Administration Permissible Exposure Limits; TWA – Time Weighted Average; HSIS – Hazardous Substances Information System; STEL – Short Term Exposure Limit; AIHA WEEL – American Industrial Hygiene Association Workplace Environment Exposure Levels; LD50 – Lethal Dose, 50%; IARC – International Agency for Research on Cancer; NTP – National Toxicology Program; WHMIS – Workplace Hazardous Materials Information System; SARA – Superfund Amendments and Reauthorization Act; EPA – Environmental Protection Agency; CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act; HIMS – Hazardous Materials Information System; NIOSH – National Institute for Occupational Safety and Health; MSHA – Mine Safety and Health Administration; ACGIH – American Conference of Governmental Industrial Hygienists; IDHL – Immediately Dangerous to Health or Life; TLV – Threshold Limit Value; HSE – Health and Safety Executive; REL - Recommended Exposure Limit

LAST REVISION
09/2016

SUPERSEDES
04/2015

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.