


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 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
RECOMMENDED USES	Manufacturing and Compounding
RESTRICTIONS ON USE	Not applicable

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 PHYSIOCHEMICAL, 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. Get emergency medical help immediately. 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.		
HMS CLASSIFICATION	Health Hazard	3	Flammability	1
	Reactivity	0	Personal Protection	G

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	2-Piperidinecarboxamide, 1-butyl-N-(2,6-dimethylphenyl)-, monohydrochloride, monohydrate, (+/-)								
BOTANICAL NAME	Not applicable								
SYNONYM	1-butyl-N-(2,6-dimethylphenyl)piperidine-2-carboxamide monohydrochloride monohydrate								
CHEMICAL FORMULA	C ₁₈ H ₂₈ N ₂ O.HCl H ₂ O								
CHEMICAL FAMILY	Piperidine derivative; amino amide								
CAS NUMBER	73360-54-0								
ALTERNATE CAS NUMBER	Not applicable								
MOLECULAR WEIGHT	342.90								
COMPOSITION	<table border="1"> <thead> <tr> <th>CHEMICAL NAME</th> <th>CAS NUMBER</th> <th>EC NUMBER</th> <th>% BY WEIGHT</th> </tr> </thead> <tbody> <tr> <td>BUPIVACAINE HCl (Monohydrate)</td> <td>73360-54-0</td> <td>241-917-8</td> <td>100</td> </tr> </tbody> </table>	CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT	BUPIVACAINE HCl (Monohydrate)	73360-54-0	241-917-8	100
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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.

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.
MEDICAL ATTENTION AND SPECIAL TREATMENT	Get emergency medical help.

SYMPTOMS CAUSED BY EXPOSURE

Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL

Emits toxic and corrosive fumes of CO, CO₂, NO_x, 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.

SUITABLE & 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.

Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40°C are acceptable.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: BUPIVACAINE HCl (Monohydrate) CAS #: 73360-54-0

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	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
GESTIS	N/A	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

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. Fumehood, eye wash station, and safety shower.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

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
(decomposes)

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)

PARTICLE CHARACTERISTICS	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
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 HCl (Monohydrate) is not listed. NTP BUPIVACAINE HCl (Monohydrate) is not listed. IARC BUPIVACAINE HCl (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	<p>ROUTES OF EXPOSURE: Oral, Dermal, Inhalation, Eye contact</p> <p>EARLY ONSET SYMPTOMS RELATED TO EXPOSURE: Due to lack of data the classification is not possible.</p> <p>DELAYED HEALTH EFFECT FROM EXPOSURE: Low blood pressure. Slow heartbeat. Irregular heartbeat. Ringing in ears. Seizures. Unconsciousness. Cardiac arrest. Coma. Death.</p> <p>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.</p> <p>Cross sensitivity: Persons sensitive to one amide-type local anesthetic may be sensitive to this material also.</p> <p>Medical conditions aggravated by exposure: Heart problems. Impaired liver function.</p> <p>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.</p>
POTENTIAL HEALTH EFFECTS	<p>Inhalation Fatal if inhaled. Causes respiratory tract irritation.</p> <p>Ingestion Fatal if swallowed.</p> <p>Skin Fatal if absorbed through skin. Causes skin irritation</p> <p>Eyes Causes eye irritation.</p>

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY	<p>EC50: 48 Hr: Crustacea: (mg/L): 39</p> <p>LC50: 96 Hr: Fish: (mg/L): Not available</p> <p>EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available</p>
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	Moderate: LogPow: 2.59 (20°C)
MOBILITY IN SOIL	Freely soluble in water
OTHER ADVERSE EFFECTS	<p>Not available</p> <p>This product is not intended to be released into the environment</p>

SECTION 13: DISPOSAL CONSIDERATIONS

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

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
BUPIVACAINE HCl (Monohydrate) 73360-54-0	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
BUPIVACAINE HCl (Monohydrate) 73360-54-0	N/L	Listed as Schedule 4*	N/L	Listed*	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
BUPIVACAINE HCl (Monohydrate) 73360-54-0	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

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

SUBJECT TO INTERNATIONAL AGREEMENT Not applicable

NOTES

*Listed as the base

SECTION 16: OTHER INFORMATION

REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

02/2024

SUPERSEDES

02/2023

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.