


SECTION 1: PRODUCT IDENTIFICATION

| | |
|----------------------------|--|
| PRODUCT NAME | DEXTROMETHORPHAN HYDROBROMIDE, USP |
| PRODUCT CODE | 0355 |
| 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 4) Eye Irritation (Category 2B) Specific Target Organ Toxicity - Single Exposure (Category 3) - respiratory tract irritation Specific Target Organ Toxicity - Single Exposure (Category 3) - narcotic effects Chronic Aquatic Toxicity (Category 2) |
| PICTOGRAM |  |
| SIGNAL WORD | Warning |
| HAZARD STATEMENT(S) | Harmful if swallowed. Causes eye irritation. May cause respiratory irritation. May cause drowsiness or dizziness. Toxic to aquatic life with long lasting effects. |
| 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.
Wash hands thoroughly after handling. Do not touch eyes.
Avoid breathing dust, fume, gas, mist, vapors and spray.
Use only outdoors or in a well-ventilated area
Avoid release to the environment.

Response

IF SWALLOWED: Immediately call a poison center. Get medical help.
Rinse mouth.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical help.
IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a poison center or doctor if Get medical help if you feel unwell
COLLECT SPILLAGE.

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

2

Flammability

0

Reactivity

0

Personal Protection

E

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS
CHEMICAL NAME

Morphinan, 3-methoxy-17-methyl-, (9alpha,13alpha,14alpha)-, hydrobromide, monohydrate

BOTANICAL NAME

Not applicable

SYNONYM

D-Methorphan hydrobromide monohydrate

CHEMICAL FORMULA

C₁₈H₂₅NO · HBr · H₂O

CHEMICAL FAMILY

Morphinan derivative

CAS NUMBER

6700-34-1 (monohydrate)

ALTERNATE CAS NUMBER

Not applicable

MOLECULAR WEIGHT

370.3282

COMPOSITION

| CHEMICAL NAME | CAS NUMBER | EC NUMBER | % BY WEIGHT |
|----------------------------------|------------|-----------|-------------|
| DEXTROMETHORPHAN HYDROBROMIDE | 6700-34-1 | 629-741-3 | 100 |

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. 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

Not applicable

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

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.

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. 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.

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.

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: DEXTROMETHORPHAN HYDROBROMIDE CAS #: 6700-34-1

| | 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: Industrial: TWA: Industrial: 10 mg/m³
SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
PHYSICAL STATE

Solid

DESCRIPTION

Practically white crystals or crystalline powder, having a faint odor. Slightly hygroscopic.

SOLUBILITY

Sparingly soluble in water; freely soluble in alcohol and in chloroform; insoluble in ether.

ODOR

Faint odor

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE

Not available

BOILING POINT

Not available

DECOMPOSITION TEMPERATURE

 (122 - 124)[°]C,
(251.6-255.2)[°]F

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

FLASH POINT

Not available

log P (OCTANOL-WATER)

 1.59 (20[°]C)

LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

MELTING/FREEZING POINT

 (122 - 124)[°]C,
(251.6-255.2)[°]F
(decomposes)

| | | | | | |
|-------------------------------------|---------------|---------------------------|---------------|---|----------------|
| PARTICLE CHARACTERISTICS | Not available | OXIDIZING PROPERTY | Not available | pH | 5.2 - 6.5 (1%) |
| RELATIVE DENSITY (WATER = 1) | Not available | SPECIFIC GRAVITY | Not available | 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, alkalis. |
| HAZARDOUS DECOMPOSITION PRODUCTS | Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides 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): 350 (anhydrous) Dermal: Rabbit: LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available |
| SKIN CORROSION/IRRITATION | Based on available data, the classification criteria are not met. Local effects. Skin irritancy test.Result: Slightly irritant. Species: Rabbit |
| SERIOUS EYE DAMAGE/EYE IRRITATION | Causes eye irritation. Local effects Eye irritancy test Result: Slightly irritant. Species: Rabbit |
| RESPIRATORY SENSITIZATION | Due to lack of data the classification is not possible. |
| SKIN SENSITIZATION | Due to lack of data the classification is not possible. |
| GERM CELL MUTAGENICITY | Due to lack of data the classification is not possible. |
| CARCINOGENICITY | OSHA DEXTROMETHORPHAN HYDROBROMIDE is not listed. NTP DEXTROMETHORPHAN HYDROBROMIDE is not listed. IARC DEXTROMETHORPHAN HYDROBROMIDE is not 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.

Reproductivity

50 mg/kg/day Reproduction and development studies in rats and rabbits, administered orally during gestation.

Result: No teratogenicity noted.

Retrospective studies

Result: No association between exposure to this material during pregnancy and an increased incidence of birth defects was seen.

Species: Human

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Respiratory tract irritation. Narcotic effects.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

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

ASPIRATION HAZARDS

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

SIGNS AND SYMPTOMS OF EXPOSURE
ROUTES OF EXPOSURE:

Ingestion, eyes, inhalation, skin

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Dizziness. Drowsiness. Headache. Unsteadiness. Seizures. Restlessness. Confusion. Hallucinations. Euphoria. Difficulty breathing. Pinpoint pupils. Uncontrolled eye movements. Nausea. Vomiting. Constipation. Urinary retention

DELAYED HEALTH EFFECT FROM EXPOSURE:

Narcosis. Psychosis. Cognitive impairment. Dependence. Respiratory depression

Cross sensitivity:

Persons sensitive to levorphanol may also be sensitive to this material.

Medical conditions aggravated by exposure:

Active alcoholism. Asthma. Respiratory disorders. Recent or concurrent use of monoamine oxidase (MAO) inhibitors. Recent or concurrent use of selective serotonin reuptake inhibitors (SSRIs).

POTENTIAL HEALTH EFFECTS

| | |
|-------------------|--|
| Inhalation | May be harmful if inhaled. May cause respiratory tract irritation. |
| Ingestion | Harmful if swallowed. |
| Skin | May be harmful if absorbed through skin. May cause skin irritation |
| Eyes | Causes eye irritation. |

SECTION 12: ECOLOGICAL INFORMATION
ECOTOXICITY

EC50: 48 Hr: Crustacea: Daphnia magna: (mg/L): 14.5

LC50: 96 Hr: Fish: (mg/L): 4.9

EC50: 72 Hr: Algae: (mg/L): 2.4

PERSISTENCE AND DEGRADABILITY

Not inherently biodegradable.

Bromide ion may be introduced to the environment after the dissociation of various salts and complexes or degradation of organobromide compounds.

BIOACCUMULATIVE POTENTIAL

LogPow: 1.59 (20°C)

MOBILITY IN SOIL

Sparingly soluble in water. 15 g/L (20°C)

OTHER ADVERSE EFFECTS

Not available

This product is not intended to be released into the environment

NOTES

Bromides may also affect the growth of micro-organisms and have been used for this purpose in industry. Bromides in drinking water are occasionally subject to disinfection processes involving ozone or chlorine. Bromide may be oxidized to produce hypobromous acid which in turn may react with natural organic matter to form brominated compounds. The formation of bromoform has been well documented, as has the formation of bromoacetic acid, bromopicrin, cyanogen and bromoacetone. Bromates may also be formed following ozonation or chlorination if pH is relatively high. Bromates may be animal carcinogens.

SECTION 13: DISPOSAL CONSIDERATIONS
DISPOSAL METHODS

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

SECTION 14: TRANSPORT INFORMATION
UN PROPER SHIPPING NAME

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

UN NUMBER

3077

CLASS

9

PACKING GROUP

III

AUSTRALIA
HAZCHEM

2Z

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 Appendix A | EPA 40 CFR Part 355 Appendix B | Pennsylvania | Right-to-know New Jersey | Massachusetts | California Prop 65 |
|---|--------------------------|-------------------------------------|--------------------------------|--------------------------------|--------------|--------------------------|---------------|--------------------|
| DEXTROMETHORPHAN HYDROBROMIDE 6700-34-1 | 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 |
|---|-------------------------------|-----------------------|---|------------------|------------------------------------|-----------------------------------|
| DEXTROMETHORPHAN HYDROBROMIDE 6700-34-1 | 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 |
|---|------------------|-----------------|--------------|-------------|--------------|---|------------|
| DEXTROMETHORPHAN HYDROBROMIDE 6700-34-1 | 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

SECTION 16: OTHER INFORMATION
REFERENCES
ABBREVIATIONS AND ACRONYMS

Available upon request

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

01/2023

SUPERSEDES

05/2021

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.