# SAFETY DATA SHEET

## SECTION 1: PRODUCT IDENTIFICATION

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>MELOXICAM, USP</th>
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<tbody>
<tr>
<td>PRODUCT CODE</td>
<td>2746</td>
</tr>
<tr>
<td>SUPPLIER</td>
<td>MEDISCA Inc.</td>
</tr>
<tr>
<td></td>
<td>MEDISCA Pharmaceutique Inc.</td>
</tr>
<tr>
<td></td>
<td>MEDISCA Australia PTY LTD</td>
</tr>
<tr>
<td>SUPPLIER (US)</td>
<td></td>
</tr>
<tr>
<td>Tel.:</td>
<td>1.800.932.1039</td>
</tr>
<tr>
<td>Fax.:</td>
<td>1.855.850.5855</td>
</tr>
<tr>
<td>Address (US)</td>
<td>661 Route 3, Unit C, Plattsburgh, NY, 12901</td>
</tr>
<tr>
<td></td>
<td>3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118</td>
</tr>
<tr>
<td></td>
<td>6641 N. Belt Line Road, Suite 130, Irving, TX, 75063</td>
</tr>
<tr>
<td></td>
<td>4509 Rue Dobrin, St. Laurent, QC, H4R 2L8</td>
</tr>
<tr>
<td></td>
<td>21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2</td>
</tr>
<tr>
<td></td>
<td>5-9 Ricketty Street, Mascot, NSW 2020</td>
</tr>
<tr>
<td>EMERGENCY PHONE</td>
<td>CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300</td>
</tr>
<tr>
<td></td>
<td>NSW Poisons Information Centre: 131 126</td>
</tr>
<tr>
<td></td>
<td>National Chemical Emergency Centre 44(0)1235239670</td>
</tr>
<tr>
<td>USES</td>
<td>Analgesic, anti-inflammatory, NSAID</td>
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## SECTION 2: HAZARDS IDENTIFICATION

### GHS CLASSIFICATION
- Acute Toxicity - Oral (Category 3)
- Toxic to Reproduction (Category 2)
- Specific Target Organ Toxicity - Repeated Exposure (Category 1) - (cardiovascular system, gastrointestinal tract)
- Chronic Aquatic Toxicity (Category 3)

### PICTOGRAM

#### SIGNAL WORD
- Danger

#### HAZARD STATEMENT(S)
- Toxic if swallowed
- Suspected of damaging fertility or the unborn child
- Causes damage to organs through prolonged or repeated exposure.
- Harmful to aquatic life with long lasting effects

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

**Prevention**
- Wash thoroughly after handling
- Do not eat, drink or smoke when using this product
- Do not breathe dust/fume/gas/mist/vapors/spray
- Observe all safety precautions before use
- Do not handle until all safety precautions have been read and understood
- Wear protective gloves, protective clothing, eye protection, face protection
- 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.

**Storage**
- Store locked up.

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

HMIS CLASSIFICATION

<table>
<thead>
<tr>
<th>Health Hazard</th>
<th>Flammability</th>
<th>Reactivity</th>
<th>Personal Protection</th>
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<tr>
<td>2</td>
<td>0</td>
<td>0</td>
<td>E</td>
</tr>
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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

**CHEMICAL NAME**
4-Hydroxy-2-methyl-N-(5-methyl-2-thiazolyl)-2H-1,2-benzothiazine-3-carboxamide 1,1-dioxide

**BOTANICAL NAME**
Not applicable

**SYNONYM**
Not available

**CHEMICAL FORMULA**
C₁₄H₁₃N₃O₄S₂

**CAS NUMBER**
71125-38-7

**ALTERNATE CAS NUMBER**
Not applicable

**MOLECULAR WEIGHT**
351.4057

**COMPOSITION**

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>EC NUMBER</th>
<th>% BY WEIGHT</th>
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<tbody>
<tr>
<td>MELOXICAM</td>
<td>71125-38-7</td>
<td>615-253-8</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: Enolic acid derivative.

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
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SPECIFIC HAZARDS ARISING FROM THE CHEMICAL

Explosion hazard: Avoid generating dust, fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

Dust explosion properties:
Minimum ignition energy (MIE) – dust cloud: 5 mJ (23.5°C)

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. Preserve in well-closed containers. Protected from light. Store at room temperature.

SPECIFIC END USE(S)

See Section 1

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: MELOXICAM    CAS #: 71125-38-7

<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>
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<tr>
<td>OSHA USA</td>
<td>N/L</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
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.

NOTES

USP: STEL 0.75 mg/m³
USP: TWA 0.15 mg/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE Solid
DESCRIPTION Pale yellow powder.
SOLUBILITY Practically insoluble in water; slightly soluble in acetone; soluble in dimethylformamide; very slightly soluble in ethanol (96%) and in methanol.
ODOR Odorless
FLAMMABILITY May be combustible at high temperature

AUTO-IGNITION TEMPERATURE 485 °C, 905 °F
BOILING POINT Not available
DECOMPOSITION TEMPERATURE (243 - 264)°C, (469.4-507.2)°F
EVAPORATION RATE Not available
EXPLOSIVE LIMIT Not available
FLASH POINT Not available

log P (OCTANOL-WATER) 0.1 (pH 7.4) (20°C)
LOWER FLAMMABLE/EXPLOSIVE LIMIT(S) Not available
MELTING/FREEZING POINT (243 - 264)°C, (469.4-507.2)°F (decomposes)
ODOR THRESHOLD Not available
OXIDIZING PROPERTY Not available
pH 5 - 7
RELATIVE DENSITY (WATER = 1) Not available
SPECIFIC GRAVITY 1.07
UPPER FLAMMABLE/EXPLOSIVE LIMIT(S) 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

**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): 83.5
- 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.
- Skin irritancy; Result: Non-irritant.; Species: Rabbit

**SERIOUS EYE DAMAGE/EYE IRRITATION**
- Based on available data, the classification criteria are not met.
- Local effects; Eye irritancy; Result: Non-irritant.; Species: Rabbit

**RESPIRATORY SENSITIZATION**
- Due to lack of data the classification is not possible.

**SKIN SENSITIZATION**
- Based on available data, the classification criteria are not met.
- Skin sensitization test; Result: Non-sensitizing.; Species: Guinea pig

**GERM CELL MUTAGENICITY**
- Due to lack of data the classification is not possible.
- Data from germ cell mutagenicity tests were not found.

**CARCINOGENICITY**
- OSHA: MELOXICAM is not listed.
- NTP: MELOXICAM is not listed.
- IARC: MELOXICAM 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**
- Based on available data, the classification criteria are not met.
**REPRODUCTIVE TOXICITY**

Suspected of damaging fertility or the unborn child.
Therapeutic use of nonsteroidal anti-inflammatory agents (NSAIDs) during the second half of pregnancy is associated with adverse effects in the fetus such as premature closure of the ductus arteriosus, which may lead to persistent pulmonary hypertension in the newborn. Animal studies have shown that NSAIDs administered during late pregnancy can cause prolonged gestation, difficult labor, delayed birth, and decreased pup survival rates.

- 60 mg/kg/day Reproductivity and development study, administered orally during organogenesis.
  - Result: Increased incidence of heart defects.
  - Species: Rabbit
- > 1 mg/kg/day Reproductivity and development study, administered orally prior to and during early gestation.
  - Result: Embryolethality.
  - Species: Rat
- >= 5 mg/kg/day Reproductivity and development study, administered orally during organogenesis.
  - Result: Embryolethality.
  - Species: Rabbit

**SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE**

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

**SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE**

Causes damage to organs (cardiovascular system, gastrointestinal tract) through prolonged or repeated exposure.

**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 any of the non-steroidal anti-inflammatory drugs, including aspirin, may be sensitive to this material also. This material may cause bronchoconstriction or anaphylaxis in aspirin-sensitive asthmatics, especially those with aspirin-induced nasal polyps, allergies, and asthma.

Medical conditions aggravated by exposure


**POTENTIAL HEALTH EFFECTS**

<table>
<thead>
<tr>
<th>Exposure</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>May be harmful if inhaled. May cause respiratory tract irritation.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Toxic if swallowed.</td>
</tr>
<tr>
<td>Skin</td>
<td>May be harmful if absorbed through skin. May cause skin irritation.</td>
</tr>
<tr>
<td>Eyes</td>
<td>May cause eye irritation.</td>
</tr>
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</table>

**SECTION 12: ECOLOGICAL INFORMATION**

**TOXICITY**

- EC50: 48 Hr: Daphnia magna: (mg/L): > 100
- LC50: 96 Hr: Fish: (mg/L): 50
- EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

**PERSISTENCE AND DEGRADABILITY**

Biodegradation: 31
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BIOACCUMULATIVE POTENTIAL
LogPow: 0.1 (pH 7.4) (20°C)

MOBILITY IN SOIL
Water Solubility: 7.150 mg/L (25°C)
Henry's Law Constant: 1.74E-19 atm-m³/mole (25°C)

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

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

UN NUMBER
2811

CLASS
6.1

PACKING GROUP
III

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

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<tr>
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<td>N/L</td>
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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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<tr>
<td>MELOXICAM, 71125-38-7</td>
<td>N/L</td>
<td>Listed as Schedule 4</td>
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N/L = Not Listed

EU REGULATIONS

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MELOXICAM, USP

SECTION 16: OTHER INFORMATION

N/L = Not Listed; X = Listed

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

REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS


LAST REVISION

02/2020

SUPERSEDES

05/2016

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.