


**SECTION 1: PRODUCT IDENTIFICATION**

|                            |  |
|----------------------------|--|
| <b>PRODUCT NAME</b>        | <b>PIROXICAM, USP</b>  |
| <b>PRODUCT CODE</b>        | <b>0302</b>  |
| <b>SUPPLIER</b>            | <b>MEDISCA Inc.</b><br>Tel.: 1.800.932.1039   Fax.: 1.855.850.5855<br>626 Tom Miller Road, Plattsburgh, NY, 12901<br><b>MEDISCA Pharmaceutique Inc.</b><br>Tel.: 1.800.665.6334   Fax.: 514.338.1693<br>4509 Rue Dobrin, St. Laurent, QC, H4R 2L8<br><b>MEDISCA Australia PTY LTD</b><br>Tel.: 1.300.786.392   Fax.: 61.2.9700.9047<br>Unit 7, Heritage Business Park<br>5-9 Ricketty Street, Mascot, NSW 2020 |
| <b>EMERGENCY PHONE</b>     | CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300<br>NSW Poisons Information Centre: 131 126<br>National Chemical Emergency Centre 44(0)1235239670   |
| <b>RECOMMENDED USES</b>    | Pharmaceutical Manufacturing   |
| <b>RESTRICTIONS ON USE</b> | Not applicable   |

**SECTION 2: HAZARDS IDENTIFICATION**

|   |  |
|---|--|
| <b>GHS CLASSIFICATION</b>   | Acute Toxicity - Oral (Category 3)<br>Toxic to Reproduction (Category 2)<br>Specific Target Organ Toxicity - Repeated Exposure (Category 1) - (cardiovascular system, gastrointestinal tract)<br>Acute Aquatic Toxicity (Category 1) |
| <b>PICTOGRAM</b>  |   |
| <b>SIGNAL WORD</b>  | Danger   |
| <b>HAZARD STATEMENT(S)</b>  | Toxic if swallowed.<br>Suspected of damaging fertility or the unborn child.<br>Causes damage to organs through prolonged or repeated exposure (cardiovascular system, gastrointestinal tract)<br>Very toxic to aquatic life.         |
| <b>ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS</b> | Not Applicable.  |

**PRECAUTIONARY STATEMENT(S)**
**Prevention**

Wash hands thoroughly after handling.  
Do not eat, drink or smoke when using this product.  
Do not breathe dust/fume/gas/mist/vapors/spray.  
Do not handle until all safety precautions have been read and understood.  
Obtain, read and follow all special instructions before use.  
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.  
Get medical help if you feel unwell.  
COLLECT SPILLAGE

**Storage**

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**

1

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

**CHEMICAL NAME**

2H-1,2-Benzothiazine-3-carboxamide, 4-hydroxy-2-methyl-N-2-pyridinyl-, 1,1-dioxide

**BOTANICAL NAME**

Not applicable

**SYNONYM**

Not applicable

**CHEMICAL FORMULA**

C<sub>15</sub>H<sub>13</sub>N<sub>3</sub>O<sub>4</sub>S

**CHEMICAL FAMILY**

Oxicam derivative; enolic acid.

**CAS NUMBER**

36322-90-4

**ALTERNATE CAS NUMBER**

Not applicable

**MOLECULAR WEIGHT**

331.3507

**COMPOSITION**

| CHEMICAL NAME | CAS NUMBER | EC NUMBER | % BY WEIGHT |
|---------------|------------|-----------|-------------|
| PIROXICAM     | 36322-90-4 | 252-974-3 | 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 &amp; UNSUITABLE EXTINGUISHING MEDIA

**Small fire:** dry chemical, CO<sub>2</sub> or water spray. **Large fire:** dry chemical, CO<sub>2</sub>, 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 &amp; 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: PIROXICAM CAS #: 36322-90-4

|        | Country     | Limit value-8 hours |                   | Limit value-Short Term |                   | IDLH | REL | Advisory | Notes |
|--------|-------------|---------------------|-------------------|------------------------|-------------------|------|-----|----------|-------|
|        |             | ppm                 | mg/m <sup>3</sup> | ppm                    | mg/m <sup>3</sup> |      |     |          |       |
| 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 | Add Country | 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/m<sup>3</sup>

#### 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 use: TWA: 0.1 mg/m<sup>3</sup>

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### PHYSICAL STATE

Solid

#### DESCRIPTION

Off-white to light tan or light yellow, odorless powder.

#### SOLUBILITY

Very slightly soluble in water, in dilute acids, and in most organic solvents; slightly soluble in alcohol and in aqueous alkaline solutions.

#### ODOR

Odorless

#### FLAMMABILITY

May be combustible at high temperature

#### AUTO-IGNITION TEMPERATURE

Not available

#### BOILING POINT

Not available

#### DECOMPOSITION TEMPERATURE

Not available

#### EVAPORATION RATE

Not available

#### EXPLOSIVE LIMIT

Not available

#### FLASH POINT

Not available

|                                     |               |   |                                    |   |  |
|-------------------------------------|---------------|---|------------------------------------|---|--|
| <b>log P (OCTANOL-WATER)</b>        | 3.06          | <b>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</b> | Not available                      | <b>MELTING/FREEZING POINT</b>             | (198 - 200) <sup>°C</sup> ,<br>(388.4-392) <sup>°F</sup> |
| <b>PARTICLE CHARACTERISTICS</b>     | Not available | <b>OXIDIZING PROPERTY</b>                 | Not available                      | <b>pH</b>                                 | Not available  |
| <b>RELATIVE DENSITY (WATER = 1)</b> | Not available | <b>SPECIFIC GRAVITY</b>                   | Not available                      | <b>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</b> | Not available  |
| <b>VAPOR DENSITY (AIR = 1)</b>      | Not available | <b>VAPOR PRESSURE</b>                     | < 0.000001 kPa (25 <sup>°C</sup> ) | <b>VISCOSITY</b>                          | Not available  |

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

## SECTION 10: STABILITY AND REACTIVITY

|  |  |
|--|--|
| <b>REACTIVITY</b>                        | Not established.   |
| <b>CHEMICAL STABILITY</b>                | Stable under recommended storage conditions.   |
| <b>INCOMPATIBLE MATERIALS</b>            | Strong oxidants.   |
| <b>HAZARDOUS DECOMPOSITION PRODUCTS</b>  | Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur. |
| <b>HAZARDOUS POLYMERIZATION</b>          | Will not occur.  |
| <b>POSSIBILITY OF HAZARDOUS REACTION</b> | Not established.   |
| <b>CONDITIONS TO AVOID</b>               | Moisture, sunlight and extreme temperatures.   |

## SECTION 11: TOXICOLOGICAL INFORMATION

|  |   |
|--|---|
| <b>ACUTE TOXICITY</b>                    | Oral: Rat: LD50: (mg/kg): 216<br>Dermal: Rat: LD50: (mg/kg): >5000<br>Inhalation: Rat: LC50: (mg/L/4hr): Not available  |
| <b>SKIN CORROSION/IRRITATION</b>         | Based on available data, the classification criteria are not met.<br>Eye irritancy test; 10 mg/mL solution administered 10 times per day<br>Result: No Irritation; Species: Rabbit; Test Duration: 7 days |
| <b>SERIOUS EYE DAMAGE/EYE IRRITATION</b> | Based on available data, the classification criteria are not met.<br>Skin irritancy test; 500 mg 10% ointment administered once<br>Result: No irritation; Species: Rabbit                                 |
| <b>RESPIRATORY SENSITIZATION</b>         | Due to lack of data the classification is not possible.   |
| <b>SKIN SENSITIZATION</b>                | Due to lack of data the classification is not possible.   |
| <b>GERM CELL MUTAGENICITY</b>            | Due to lack of data the classification is not possible.   |
| <b>CARCINOGENICITY</b>                   | <b>OSHA</b> PIROXICAM is not listed.<br><b>NTP</b> PIROXICAM is not listed.<br><b>IARC</b> PIROXICAM is not evaluated.  |

**ADDITIONAL CARCINOGENICITY INFORMATION**
**REPRODUCTIVE TOXICITY**
**SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE**
**SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE**
**ASPIRATION HAZARDS**
**SIGNS AND SYMPTOMS OF EXPOSURE**
**POTENTIAL HEALTH EFFECTS**
**California Proposition**

This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

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

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.

Mouse: 0.3 - 30 mg/kg/day Reproductivity, administered orally during gestation; Result: Maternal and fetal toxicity.

Rabbit: 10 mg/kg/day Developmental, administered orally; Result: NOAEL = 10 mg/kg/day; not teratogenic.

Rat: 10 mg/kg/day Developmental, administered orally; Result: NOAEL = 10 mg/kg/day; not teratogenic.

Suspected toxic for reproduction: CAESAR developmental toxicity model in VEGA (Q)SAR platform predicts that the chemical is Toxicant (moderate reliability).

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

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

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

**ROUTES OF EXPOSURE:**

Oral, Dermal, Inhalation, Eye contact

**EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:**

Not available

**DELAYED HEALTH EFFECT FROM EXPOSURE:**

For nonsteroidal anti-inflammatory drugs (NSAIDs):

Gastrointestinal ulceration or bleeding. Hypertension. Kidney impairment. Blood disorders. Cardiovascular thrombotic events. Stroke. Central nervous system effects. Coma.

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

For nonsteroidal anti-inflammatory drugs (NSAIDs): Nausea. Vomiting. Diarrhea. Constipation. Heartburn. Stomach pain. Black or tarry stools. Bleeding or bruising. Swelling. Sores, ulcers, or white spots on lips or mouth. Sweating. Bluish-colored skin. Insomnia. Mood, mental or behavioral changes. Confusion. Dizziness. Drowsiness. Headache. Itching. Rash. Weight gain. Vision, speech, or walking problems. Ringing in ears. Tremors. Trouble breathing. Fast heartbeat or palpitations.

**Cross sensitivity:**

Persons sensitive to one nonsteroidal anti-inflammatory drug (NSAID), including aspirin, may be sensitive to this material also.

**Medical conditions aggravated by exposure:**

For nonsteroidal anti-inflammatory drugs (NSAIDs): Asthma. Aspirin allergy. Active alcoholism. Anemia. Impaired kidney or liver function. Cardiovascular disorders. Bleeding disorders. Peptic ulcer or gastrointestinal bleeding. Hypertension. Stomatitis.

**Inhalation**

Harmful if inhaled. May cause respiratory tract irritation.

**Ingestion**

Toxic if swallowed.

**Skin**

May be harmful if absorbed through skin. May cause skin irritation.

**Eyes**

May cause eye irritation.

**SECTION 12: ECOLOGICAL INFORMATION**

|                                      |   |
|--------------------------------------|---|
| <b>ECOTOXICITY</b>                   | EC50: 48 Hr: Crustacea: Daphnia Magna: (mg/L): 1.48*<br>LC50: 96 Hr: Fish: (mg/L): 12.44*<br>EC50: 96 Hr: Algae: (mg/L): 1.14*  |
| <b>PERSISTENCE AND DEGRADABILITY</b> | Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable.               |
| <b>BIOACCUMULATIVE POTENTIAL</b>     | LogPow: 3.06  |
| <b>MOBILITY IN SOIL</b>              | Very slightly soluble in water<br>Water Solubility: 23 mg/L (22°C)<br>Vapor Pressure: 4.67E-15 mm Hg (25°C)<br>Henry's Law Constant: 2.90E-19 atm-m <sup>3</sup> /mole (25°C) |
| <b>OTHER ADVERSE EFFECTS</b>         | Not available.  |
| <b>NOTES</b>                         | This product is not intended to be released into the environment.<br>*Danish QSAR database  |

**SECTION 13: DISPOSAL CONSIDERATIONS**

|                         |   |
|-------------------------|---|
| <b>DISPOSAL METHODS</b> | Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment. |
|-------------------------|---|

**SECTION 14: TRANSPORT INFORMATION**

|  |                              |
|--|------------------------------|
| <b>UN PROPER SHIPPING NAME</b>   | TOXIC SOLID, ORGANIC, N.O.S. |
| <b>UN NUMBER</b>   | 2811                         |
| <b>CLASS</b>   | 6.1                          |
| <b>PACKING GROUP</b>   | III                          |
| <b>AUSTRALIA HAZCHEM</b>   | 2X                           |
| <b>EU TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE</b> | Not Listed                   |
| <b>ENVIRONMENTAL HAZARDS</b>   | Not available                |
| <b>SPECIAL SHIPPING INFORMATION</b>  | Not applicable               |

**SECTION 15: REGULATORY INFORMATION****UNITED STATES REGULATIONS**

| Chemical Name & CAS   | CERCLA 40 CFR Part 302.4 | SARA (Title III) 40 CFR | EPA 40 CFR Part 355 Appendix A Appendix B |     | Pennsylvania | Right-to-know New Jersey | Massachusetts | California Prop 65 |
|-----------------------|--------------------------|-------------------------|---|-----|--------------|--------------------------|---------------|--------------------|
| PIROXICAM, 36322-90-4 | 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 | Poisons Standard | Work Health and Safety Regulations | Inventory of Industrial Chemicals |
|-----------------------|-------------------------------|-----------------------|----------------------------------|------------------|------------------------------------|-----------------------------------|
| PIROXICAM, 36322-90-4 | 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 |
|-----------------------|------------------|-----------------|--------------|-------------|--------------|---|------------|
| PIROXICAM, 36322-90-4 | 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**

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**

07/2023

**SUPERSEDES**

05/2021

For a list of changes to the SDS since the last version, please communicate with MEDISCA at [www.medisca.com](http://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.