# SAFETY DATA SHEETS

## According to the UN GHS revision 8

Version: 1.0
Creation Date: July 15, 2024
Revision Date: July 15, 2024

## 1. Identification

### 1.1 GHS Product identifier

**Product name** Metronidazole

### 1.2 Other means of identification

**Product number** M80002

**Other names**

### 1.3 Recommended use of the chemical and restrictions on use

**Identified uses** Veterinary Drug: ANTIPROTOZOAL_AGENT

**Uses advised against** no data available

### 1.4 Supplier's details

**Company** Tianjin Psaitong Biomedical Technology Co., Ltd
Beijing Psaitong Biotechnology Co., Ltd

**Address** Building 145, Yougu New Science Park, Qingguang Town, Beichen District, Tianjin City

**Tel/Fax** +86-10-60605840

### 1.5 Emergency phone number

**Emergency phone number** +86-10-60605840

**Service hours** Monday to Friday, 9am-5pm (Standard time zone: UTC/GMT +8 hours).

## 2. Hazard identification

### 2.1 Classification of the substance or mixture

Germ cell mutagenicity, Category 2
Carcinogenicity, Category 1B
Specific target organ toxicity – repeated exposure, Category 2

### 2.2 GHS label elements, including precautionary statements

**Pictogram(s)**

**Signal word** Danger

**Hazard statement(s)** H341 Suspected of causing genetic defects
H350 May cause cancer
H373 May cause damage to organs through prolonged or repeated exposure

**Precautionary statement(s)**

**Prevention** P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.

| | |
|---|---|
| | P280 Wear protective gloves/protective clothing/eye protection/face protection.<br>P260 Do not breathe dust/fume/gas/mist/vapours/spray. |
| **Response** | P308+P313 IF exposed or concerned: Get medical advice/ attention.<br>P314 Get medical advice/attention if you feel unwell. |
| **Storage** | P405 Store locked up. |
| **Disposal** | P501 Dispose of contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal. |

### 2.3 Other hazards which do not result in classification

no data available

## 3. Composition/information on ingredients

### 3.1 Substances

| Chemical name | Common names and synonyms | CAS number | EC number | Concentration |
|---|---|---|---|---|
| Metronidazole | Metronidazole | 443-48-1 | 207-136-1 | 100% |

## 4. First-aid measures

### 4.1 Description of necessary first-aid measures

**General advice**

Medical attention is required. Consult a doctor. Show this safety data sheet (SDS) to the doctor in attendance.

**If inhaled**

Move the victim into fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration and consult a doctor immediately. Do not use mouth to mouth resuscitation if the victim ingested or inhaled the chemical.

**Following skin contact**

Take off contaminated clothing immediately. Wash off with soap and plenty of water. Consult a doctor.

**Following eye contact**

Rinse with pure water for at least 15 minutes. Consult a doctor.

**Following ingestion**

Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Call a doctor or Poison Control Center immediately.

### 4.2 Most important symptoms/effects, acute and delayed

SYMPTOMS: Symptoms of exposure to this chemical may include nerve or sheath structural changes, eye changes, tremors, fever, jaundice and other liver changes. It may cause convulsive seizures, numbness, nausea, vomiting, abdominal discomfort, diarrhea, sharp, unpleasant metallic taste, erythematous rash, pruritus, dizziness, syncope, ataxia, thrombophlebitis after intravenous infusion, darkened urine, anorexia, epigastric distress, constipation, glossitis, stomatitis, reversible thrombocytopenia and vertigo. Flattening of the T-wave may be seen in electrocardiographic tracings. It may also cause incoordination, irritability, depression, weakness, insomnia, nasal congestion dysuria, cystitus, polyuria, incontinence, a sense of pelvic pressure, dyspareunia, decrease of libido, proctitis and fleeting joint pains sometimes resembling serum sickness. It may cause skin rash and drowsiness. Other symptoms of exposure include malaise, transient rashes, gastrointestinal disturbances and peripheral neuropathy. It may cause coated tongue, dry mouth, urethral discomfort, temporary leukopenia, increase in chromosome aberrations, candidal vaginitis, lethargy and sore furred tongue. In conjunction with alcohol it may provoke a disulfuram-like reaction. Pregnant women expose to this compound have given birth to premature, stillborn infants. One infant has died of white asphyxia. It may cause epigastric distress, abdominal cramping, numbness or paresthesia of an extremity, urticaria, flushing, dryness of vagina or vulva, abdominal distress, headache (if ingested with alcohol), confusional and psychotic states, blood dyscrasias, temporary neutropenia which reverses after therapy, and low concentrations of lipids in plasma. ACUTE/CHRONIC HAZARDS: This compound is harmful by ingestion, inhalation or skin absorption. It may cause irritation. When heated to decomposition it emits toxic fumes of carbon monoxide, carbon dioxide and nitrogen oxides. (NTP, 1992)

### 4.3 Indication of immediate medical attention and special treatment needed, if necessary

Maintain an open airway and assist ventilation if necessary. Treat coma, seizures, hypotension, anaphylaxis, and hemolysis if they occur. Replace fluid losses resulting from gastroenteritis with intravenous crystalloids. ... Administer activated charcoal. Gastric emptying is not necessary if activated charcoal can be given promptly. Most antibiotics are excreted unchanged in the urine, so maintenance of adequate urine flow is important. The role of forced diuresis is unclear. Hemodialysis is not usually indicated, except perhaps in patients with renal dysfunction and a high level of toxic agent. Antibacterial Agents

# 5. Fire-fighting measures

## 5.1 Extinguishing media

**Suitable extinguishing media**

Fires involving this material can be controlled with a dry chemical, carbon dioxide or Halon extinguisher. (NTP, 1992)

## 5.2 Specific hazards arising from the chemical

Flash point data for this chemical are not available; however, it is probably combustible. (NTP, 1992)

## 5.3 Special protective actions for fire-fighters

Wear self-contained breathing apparatus for firefighting if necessary.

# 6. Accidental release measures

## 6.1 Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Avoid breathing mist, gas or vapours.Avoid contacting with skin and eye. Use personal protective equipment.Wear chemical impermeable gloves. Ensure adequate ventilation.Remove all sources of ignition. Evacuate personnel to safe areas.Keep people away from and upwind of spill/leak.

## 6.2 Environmental precautions

Prevent further spillage or leakage if it is safe to do so. Do not let the chemical enter drains. Discharge into the environment must be avoided.

## 6.3 Methods and materials for containment and cleaning up

PRECAUTIONS FOR "CARCINOGENS": A high-efficiency particulate arrestor (HEPA) or charcoal filters can be used to minimize amt of carcinogen in exhausted air ventilated safety cabinets, lab hoods, glove boxes or animal rooms ... Filter housing that is designed so that used filters can be transferred into plastic bag without contaminating maintenance staff is avail commercially. Filters should be placed in plastic bags immediately after removal ... The plastic bag should be sealed immediately ... The sealed bag should be labelled properly ... Waste liquids ... should be placed or collected in proper containers for disposal. The lid should be secured & the bottles properly labelled. Once filled, bottles should be placed in plastic bag, so that outer surface ... is not contaminated ... The plastic bag should also be sealed & labelled. ... Broken glassware ... should be decontaminated by solvent extraction, by chemical destruction, or in specially designed incinerators. Chemical Carcinogens

# 7. Handling and storage

## 7.1 Precautions for safe handling

Handling in a well ventilated place. Wear suitable protective clothing. Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Use non-sparking tools. Prevent fire caused by electrostatic discharge steam.

## 7.2 Conditions for safe storage, including any incompatibilities

PRECAUTIONS FOR "CARCINOGENS": Storage site should be as close as practical to lab in which carcinogens are to be used, so that only small quantities required for ... expt need to be carried. Carcinogens should be kept in only one section of cupboard, an explosion-proof refrigerator or freezer (depending on chemicophysical properties ...) that bears appropriate label. An inventory ... should be kept, showing quantity of carcinogen & date it was acquired ... Facilities for dispensing ... should be contiguous to storage area. Chemical Carcinogens

# 8. Exposure controls/personal protection

## 8.1 Control parameters

**Occupational Exposure limit values**

| | |
|---|---|
| **Component** | Metronidazole |
| **CAS No.** | 443-48-1 |

| | Limit value - Eight hours | | Limit value - Short term | |
|---|---|---|---|---|
| | ppm | mg/m$^3$ | ppm | mg/m$^3$ |
| The Netherlands | | 0,00012 | | |
| | Remarks | | | |

### 8.2 Appropriate engineering controls

Ensure adequate ventilation. Handle in accordance with good industrial hygiene and safety practice. Set up emergency exits and the risk-elimination area.

### 8.3 Individual protection measures, such as personal protective equipment (PPE)

**Eye/face protection**

Wear tightly fitting safety goggles with side-shields conforming to EN 166(EU) or NIOSH (US).

**Skin protection**

Wear fire/flame resistant and impervious clothing. Handle with gloves. Gloves must be inspected prior to use. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

**Respiratory protection**

If the exposure limits are exceeded, irritation or other symptoms are experienced, use a full-face respirator.

**Thermal hazards**

no data available

## 9. Physical and chemical properties

| | |
|---|---|
| **Physical state** | PHYSICAL DESCRIPTION: White to pale-yellow crystalline powder with a slight odor. Bitter and saline taste. pH (saturated aqueous solution) about 6.5. (NTP, 1992) |
| **Colour** | Cream-colored crystals |
| **Odour** | ODORLESS |
| **Melting point/ freezing point** | 206°C(lit.) |
| **Boiling point or initial boiling point and boiling range** | 254°C(lit.) |
| **Flammability** | no data available |
| **Lower and upper explosion limit / flammability limit** | no data available |
| **Flash point** | 9°C |
| **Auto-ignition temperature** | no data available |
| **Decomposition temperature** | no data available |
| **pH** | pH of saturated aq soln is 5.8 |
| **Kinematic viscosity** | no data available |
| **Solubility** | >25.7 [ug/mL] |
| **Partition coefficient n-octanol/water** | no data available |
| **Vapour pressure** | 2.67E-07mmHg at 25°C |
| **Density and/or relative density** | 1.45 g/cm3 |
| **Relative vapour density** | no data available |
| **Particle characteristics** | no data available |

## 10. Stability and reactivity

### 10.1 Reactivity

no data available

### 10.2 Chemical stability

Stable in air but darkens on exposure to light.

### 10.3 Possibility of hazardous reactions

METRONIDAZOLE darkens on exposure to light. This chemical is incompatible with strong oxidizing agents. (NTP, 1992).

### 10.4 Conditions to avoid

no data available

### 10.5 Incompatible materials

Because reconstituted metronidazole hydrochloride solution has a low pH, the solution may interact with aluminum resulting in a reddish-brown discoloration of the solution. Therefore, aluminum hub needles should not be used to reconstitute the drug or to transfer the reconstituted solution to the diluting fluid. Metronidazole hydrochloride that has been reconstituted, diluted, and neutralized and metronidazole injection do not interact with aluminum when administered over the time period specified by the manufacturers; however, some discoloration of these solutions may occur when they are in contact with aluminum for periods of 6 hours or longer.

### 10.6 Hazardous decomposition products

no data available

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## 11. Toxicological information

**Acute toxicity**

- Oral: LD50 Albino Rat oral > 5 g/kg
- Inhalation: no data available
- Dermal: no data available

**Skin corrosion/irritation**

no data available

**Serious eye damage/irritation**

no data available

**Respiratory or skin sensitization**

no data available

**Germ cell mutagenicity**

no data available

**Carcinogenicity**

Metronidazole: reasonably anticipated to be a human carcinogen.

**Reproductive toxicity**

no data available

**STOT-single exposure**

no data available

**STOT-repeated exposure**

no data available

**Aspiration hazard**

no data available

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## 12. Ecological information

### 12.1 Toxicity

- Toxicity to fish: LC50 Lepomis macrochirus (Bluegill sunfish, weight 0.1g) >100 ppm/96 hr; static /99.4% AI formulated product
- Toxicity to daphnia and other aquatic invertebrates: EC50 Daphnia magna (Water flea, age <24 hr; intoxication, immobilization)

>1000 ppm/48 hr; static /99% AI formulated product

- Toxicity to algae: EC50 Pseudokirchneriella subcapitata (Green algae; decreased population growth) 40.4 mg/L/72 hr (95% confidence limit: 2.17-750 mg/L); static
- Toxicity to microorganisms: no data available

### 12.2 Persistence and degradability

AEROBIC: The biodegradation half-lives in sandy soil-manure slurry were 9.7 to 14.7 days and in clay soil-manure slurry were 13.1 to 26.9 days(1). Metronidazole was found to be non-degradable in sewage treatment conditions(2). Metronidazole did not degrade in closed bottle tests at concentrations of 5.95 ug/L and 5.95 mg/L(3).

### 12.3 Bioaccumulative potential

An estimated BCF of 3 was calculated for metronidazole(SRC), using a log Kow of -0.02(1) and a regression-derived equation(2). According to a classification scheme(3), this BCF suggests the potential for bioconcentration in aquatic organisms is low(SRC).

### 12.4 Mobility in soil

The Koc of metronidazole is estimated as 23(SRC), using a log Kow of -0.02(1) and a regression-derived equation(2). According to a classification scheme(3), this estimated Koc value suggests that metronidazole is expected to have very high mobility in soil.

### 12.5 Other adverse effects

no data available

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## 13. Disposal considerations

### 13.1 Disposal methods

**Product**

The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems.

**Contaminated packaging**

Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.

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## 14. Transport information

### 14.1 UN Number

| ADR/RID | IMDG | IATA |
|---|---|---|
| Not dangerous goods. (For reference only, please check.) | Not dangerous goods. (For reference only, please check.) | Not dangerous goods. (For reference only, please check.) |

### 14.2 UN Proper Shipping Name

| ADR/RID | IMDG | IATA |
|---|---|---|
| Not dangerous goods. (For reference only, please check.) | Not dangerous goods. (For reference only, please check.) | Not dangerous goods. (For reference only, please check.) |

### 14.3 Transport hazard class(es)

| ADR/RID | IMDG | IATA |
|---|---|---|
| Not dangerous goods. (For reference only, please check.) | Not dangerous goods. (For reference only, please check.) | Not dangerous goods. (For reference only, please check.) |

### 14.4 Packing group, if applicable

| ADR/RID | IMDG | IATA |
|---|---|---|
| Not dangerous goods. (For reference only, please check.) | Not dangerous goods. (For reference only, please check.) | Not dangerous goods. (For reference only, please check.) |

### 14.5 Environmental hazards

| ADR/RID | IMDG | IATA |
|---|---|---|
| No | No | No |

### 14.6 Special precautions for user

no data available

### 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

no data available

## 15. Regulatory information

### 15.1 Safety, health and environmental regulations specific for the product in question

| Chemical name | Common names and synonyms | CAS number | EC number |
|---|---|---|---|
| Metronidazole | Metronidazole | 443-48-1 | 207-136-1 |
| **European Inventory of Existing Commercial Chemical Substances (EINECS)** | | | Listed. |
| **EC Inventory** | | | Listed. |
| **United States Toxic Substances Control Act (TSCA) Inventory** | | | Not Listed. |
| **China Catalog of Hazardous chemicals 2015** | | | Not Listed. |
| **New Zealand Inventory of Chemicals (NZIoC)** | | | Listed. |
| **Philippines Inventory of Chemicals and Chemical Substances (PICCS)** | | | Listed. |
| **Vietnam National Chemical Inventory** | | | Listed. |
| **Chinese Chemical Inventory of Existing Chemical Substances (China IECSC)** | | | Listed. |
| **Korea Existing Chemicals List (KECL)** | | | Listed. |

## 16. Other information

**Information on revision**

| | |
|---|---|
| **Creation Date** | July 15, 2024 |
| **Revision Date** | July 15, 2024 |

**Abbreviations and acronyms**

- CAS: Chemical Abstracts Service
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- RID: Regulation concerning the International Carriage of Dangerous Goods by Rail
- IMDG: International Maritime Dangerous Goods
- IATA: International Air Transportation Association
- TWA: Time Weighted Average
- STEL: Short term exposure limit
- LC50: Lethal Concentration 50%
- LD50: Lethal Dose 50%
- EC50: Effective Concentration 50%

**References**


- IPCS - The International Chemical Safety Cards (ICSC), website: http://www.ilo.org/dyn/icsc/showcard.home
- HSDB - Hazardous Substances Data Bank, website: https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm
- IARC - International Agency for Research on Cancer, website: http://www.iarc.fr/
- eChemPortal - The Global Portal to Information on Chemical Substances by OECD, website: http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en
- CAMEO Chemicals, website: http://cameochemicals.noaa.gov/search/simple
- ChemIDplus, website: http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp
- ERG - Emergency Response Guidebook by U.S. Department of Transportation, website: http://www.phmsa.dot.gov/hazmat/library/erg
- Germany GESTIS-database on hazard substance, website: http://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index-2.jsp
- ECHA - European Chemicals Agency, website: https://echa.europa.eu/


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