

# SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078947205

N/A



# SAFETY DATA SHEET

## SECTION 1: IDENTIFICATION OF THE PRODUCT & THE COMPANY

a) <b>Product Name :</b>	Metronidazole Injection
b) <b>Chemical Family :</b>	Mixture
c) <b>Common/ trade Name :</b>	Metronidazole Injection
d) <b>Product :</b>	Finished pharmaceutical product
<b>Recommended Use:</b>	Pharmaceutical product used as antiprotozoal agent
<b>Manufacture Name:</b>	<b>Gland pharma Limited</b>
<b>Address:</b>	Survey No.: 143–148, 150 & 151 Near Gandimaisamma Cross Roads, D.P.Pally, Quthbullapur Mandal Ranga Reddy District Hyderabad- 500043 Telangana, India
<b>Telephone Number for Info:</b>	+91-40-30510999

## SECTION 2: HAZARDS IDENTIFICATION

<b>Appearance:</b>	Liquid
<b>Statement of Hazard:</b>	Non-hazardous in accordance with international standards for workplace safety.
<b>Additional Hazard Information:</b>	
<b>Short Term:</b>	Ingestion of large amounts may cause central nervous system effects.
<b>Long Term:</b>	Animal studies have shown a potential to cause adverse effects on the Foetus. Suspected of causing cancer.
<b>Known Clinical Effects:</b>	Clinical use of this drug has caused peripheral neuropathy, associated with numbness and tingling of the extremities, pain, and motor weakness. Effects on blood and blood-forming organs have also occurred.
<b>EU Indication of danger:</b>	Not classified
<b>Note:</b>	This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.



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## SECTION 3 – COMPOSITION/ INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Metronidazole	443-48-1	207-136-1	Xn;R40-63	0.5
Citric Acid	77-92-9	201-069-1	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Sodium phosphate, dibasic	7558-79-4	231-448-7	Not Listed	*
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Water for Injection	7732-18-5	231-791-2	Not Listed	*

**Additional Information:** \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

**For the full text of the R phrases mentioned in this Section, see Section 16**

## SECTION 4 - FIRST AID MEASURES

**Eye Contact :** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact :** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Inhalation :** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Ingestion :** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.



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**Symptoms and Effects of Exposure :** For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

## **SECTION 5: FIRE-FIGHTING MEASURES**

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.  
**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.  
**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.  
**Fire / Explosion Hazards:** Not applicable

## **SECTION 6: ACCIDENTAL RELEASE MEASURES**

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.  
**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.  
**Measures for Environmental Protections:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.  
**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

## **SECTION 7: HANDLING AND STORAGE**

**General Handling:** Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.  
**Storage Conditions:** Store as directed by product packaging.



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## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

### Metronidazole

Netherlands OEL – TWA Listed

### Sodium chloride

Latvia OEL - TWA Listed

Lithuania OEL – TWA Listed

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

### Engineering Controls:

General room ventilation is adequate unless the process generates dust, mist or fumes. Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section.

### Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community environmental legislation.

### Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

### Hands:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

### Eyes:

Wear safety glasses or goggles if eye contact is possible.

### Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

### Respiratory protection:

If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.



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## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:** Liquid  
**Color :** No data available.  
**Molecular Formula:** Mixture  
**Molecular Weight:** Mixture

## SECTION 10: STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.  
**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

## SECTION 11: TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

### Acute Toxicity: (Species, Route, End Point, Dose)

#### **Metronidazole**

Rat	Oral	LD 50	3 g/kg
Mouse	Oral	LD 50	3800 mg/kg
Mouse	Intraperitoneal	LD 50	870 mg/kg

#### **Sodium phosphate, dibasic**

Rat	Oral	LD 50	17 g/kg
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#### **Sodium chloride**

Rat	Oral	LD50	3000 mg/kg
Mouse	Oral	LD50	4000 mg/kg

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

### Irritation / Sensitization: (Study Type, Species, Severity)

#### **Metronidazole**

Eye Irritation	Rabbit	No effect
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## Citric Acid

Eye Irritation     Rabbit   Irritant  
 Skin Irritation    Rabbit   Non-irritating

## Sodium phosphate, dibasic

Eye Irritation     Rabbit   Mild  
 Skin Irritation    Rabbit   Mild

## Sodium chloride

Eye Irritation     Rabbit   Moderate  
 Skin Irritation    Rabbit   Mild

### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

#### Metronidazole

2 Year(s)	Mouse	Oral	600 mg/kg	LOAEL	
80 Week(s)	Rat	Oral	30 mg/kg	LOAEL	
34 Day(s)	Rat	Oral	= 34 g/kg	LOAEL	Kidney Ureter Bladder
4 Month(s)	Dog	Oral	75 mg/kg	LOAEL	
1 Year(s)	Non-human Primate	Oral	150 mg/kg	LOAEL	

**Repeated Dose Toxicity Comments:** Metronidazole produced tumors in mice and rats.

### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

#### Metronidazole

Reproductive & Fertility	Rat	Oral	400 mg/kg	LOAEL	Fertility
Reproductive & Fertility	Rabbit	Oral	200 mg/kg	NOAEL	Fertility, Developmental toxicity, Fetotoxicity
Embryo / Fetal Development	Mouse	Intraperitoneal	9 mg/kg	LOAEL	Fetotoxicity
Embryo / Fetal Development	Rat	Oral	200 mg/kg	NOEL	Not Teratogenic
Embryo / Fetal Development	Mouse	Intraperitoneal	40 mg/kg	LOAEL	Fetotoxicity

### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

#### Metronidazole

<i>In Vitro</i> Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Positive
<i>In Vitro</i> Sister Chromatid Exchange	Hamster	Negative
<i>In Vivo</i> Unscheduled DNA Synthesis	Rabbit	Negative
<i>In Vivo</i> Micronucleus	Rat	Negative
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Negative



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## Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

### Metronidazole

Not specified	Rat	Oral	Tumors
Not specified	Mouse	Oral	Tumors

**Carcinogen Status:** See below

### Metronidazole

<b>IARC:</b>	Group 2B
<b>NTP:</b>	Listed
<b>OSHA:</b>	Present

## SECTION 12: ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties of the formulation have not been thoroughly investigated.

## Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

### Metronidazole

Mysid Shrimp	OECD	LC-50	96 Hours	>180 mg/L
Sheepshead Minnow	OECD	LC-50	96 Hours	>1060 mg/L

**Aquatic Toxicity Comments:** A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

## SECTION 13: DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

## SECTION 14: TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## SECTION 15: REGULATORY INFORMATION

**EU Indication of danger:** Not classified





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**OSHA Label:**

Non-hazardous in accordance with international standards for workplace safety.

**Canada - WHMIS: Classifications****WHMIS hazard class:**

Class D, Division 2, Subdivision A

**Metronidazole**

<b>California Proposition 65</b>	Listed; Cancer
<b>Australia (AICS):</b>	Listed
<b>Standard for the Uniform Scheduling for Drugs and Poisons:</b>	Schedule 4
<b>EU EINECS/ELINCS List</b>	207-136-1

**Citric Acid**

<b>Inventory - United States TSCA - Sect. 8(b)</b>	Listed
<b>Australia (AICS):</b>	Listed
<b>EU EINECS/ELINCS List</b>	201-069-1

**Sodium phosphate, dibasic**

<b>CERCLA/SARA Hazardous Substances and their Reportable Quantities:</b>	2270 kg final RQ 5000 lb final RQ
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Listed
<b>Australia (AICS):</b>	Listed
<b>EU EINECS/ELINCS List</b>	231-448-7

**Sodium chloride**

<b>Inventory - United States TSCA - Sect. 8(b)</b>	Listed
<b>Australia (AICS):</b>	Listed
<b>EU EINECS/ELINCS List</b>	231-598-3

**Water for Injection**

<b>Inventory - United States TSCA - Sect. 8(b)</b>	Listed
<b>Australia (AICS):</b>	Listed
<b>REACH - Annex IV - Exemptions from the obligations of Register:</b>	Present
<b>EU EINECS/ELINCS List</b>	231-791-2



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## **SECTION 16: OTHER INFORMATION:**

### **Text of R phrases mentioned in Section 3**

R40 - Limited evidence of a carcinogenic effect

R63 - Possible risk of harm to the unborn child.

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANYKIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULARPURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

**Glossary:** This glossary contains definitions of general terms used in SDSs. Not all of these Glossary terms will apply to this SDS.

AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient



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LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable,
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
IOEL	International Occupational Exposure Limit
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act



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TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations

**Date of issue for current version:** 03 November 2021

**Next review date:** Whenever there is a change in the content. No defined review period for SDS

**End of safety data sheet**