Metronidazole Injection, USP

Safety Data Sheet

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SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Metronidazole Injection, USP

1.2. Intended Use of the Product

Use of the Substance/Mixture: Metronidazole is classified as a nitroimidazole antimicrobial and is administered by the intravenous route.

1.3. Name, Address, and Telephone of the Responsible Party

Company

WG Critical Care, LLC
120 Route 17 North, Suite 115
Paramus, NJ 07652 USA
+ 1-888-493-0861
wgccquality@wgcriticalcare.com
https://www.wgcriticalcare.com/

1.4. Emergency Telephone Number

Emergency Number : +1-866-562-4708 (ProPharma)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US Classification

Carcinogenicity Category 2	H351
Reproductive toxicity Category 2	H361

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US) :

GHS08

Signal Word (GHS-US) : Warning

Hazard Statements (GHS-US) : H351 - Suspected of causing cancer (oral).
H361 - Suspected of damaging fertility or the unborn child (oral).

Precautionary Statements (GHS-US) : 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, and eye protection.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P405 - Store locked up.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	%	GHS US classification
Water	AQUA	(CAS-No.) 7732-18-5	98 – 99	Not classified.

Metronidazole	Imidazole, 1-(2-hydroxyethyl)-2-methyl-5-nitro- Imidazole-1-ethanol, 2-methyl-5-nitro- 1H-Imidazole-1-ethanol, 2-methyl-5-nitro- NSC-50364 2-Methyl-5-nitro-1H-imidazole-1-ethanol 1-(2-Methyl-5-nitro-1H-imidazol-1-yl)ethanol metronidazole	(CAS-No.) 443-48-1	0.1 – 1	Muta. 2, H341 Carc. 2, H351 Repr. 2, H361 Aquatic Acute 2, H401 Aquatic Chronic 3, H412
Sodium chloride	Sodium salt of hydrochloric acid Salt SEA SALT SODIUM CHLORIDE Sodium chloride (NaCl) Sea salt	(CAS-No.) 7647-14-5	0.1 – 1	Not classified.
Phosphoric acid, disodium salt	Sodium phosphate dibasic Disodium hydrogen phosphate Disodium hydrogenorthophosphate Disodium phosphate Sodium phosphate, dibasic Disodium phosphate, anhydrous Phosphoric acid, sodium salt (1:2) DISODIUM PHOSPHATE Disodium hydrogen orthophosphate Disodium orthophosphate sodium phosphate, dibasic, anhydrous	(CAS-No.) 7558-79-4	0.1 – 1	Not classified.
Citric acid	1,2,3-Propanetricarboxylic acid, 2-hydroxy- CITRIC ACID 2-Hydroxypropane-1,2,3-tricarboxylic acid Anhydrous citric acid 2-Hydroxy-1,2,3-propanetricarboxylic acid Citric acid, anhydrous	(CAS-No.) 77-92-9	0.1 – 1	Eye Irrit. 2A, H319 STOT SE 3, H335 Comb. Dust

* The actual concentration of ingredient(s) is withheld as a trade secret in accordance with the 29 CFR 1910.1200. Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%). Full text of H-phrases: see section 16.

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Wash with plenty of soap and water. If exposed or concerned: Get medical advice/attention.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: Suspected of damaging fertility or the unborn child (if swallowed). Suspected of causing cancer (if swallowed).

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Suspected of causing cancer (if swallowed). May damage fertility or the unborn child (if swallowed).

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Solutions do not burn. Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: None known.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Product is not flammable.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Oxides of carbon, nitrogen, phosphorous, and sodium. . Chlorine compounds.

Other Information: No additional information available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not get in eyes, on skin, or on clothing. Do not breathe vapor, mist or spray. If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Material may be biologically contaminated with pathogenic organisms during use.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get in eyes, on skin, or on clothing. Do not breathe vapor, mist, or spray. Contaminated sharps should be handled with care and discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a syringe disposal program. In hospital and workplace settings, contaminated sharps are to be handled in accordance with EC Directive 2010/32/EU.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store locked up/in a secure area. Store at controlled room temperature (20-25 °C / 68-77 °F).

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s)

Metronidazole is classified as a nitroimidazole antimicrobial and is administered by the intravenous route.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

8.2. Exposure Controls

Appropriate Engineering Controls : Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment : Gloves. Protective clothing. Protective goggles or glasses. Insufficient ventilation: wear respiratory protection.

Materials for Protective Clothing : Chemically resistant materials and fabrics.

Hand Protection : Wear protective gloves.

Eye and Face Protection : Chemical goggles or safety glasses.

Skin and Body Protection : Wear suitable protective clothing.

Respiratory Protection : If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Thermal Hazard Protection : Not applicable.

Environmental Exposure Controls : Avoid unnecessary release into the environment.

Other Information : When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State : Liquid

Appearance : Clear, pale yellow liquid

Odor : Very slight

Odor Threshold : No data available

pH : 5.0 – 5.5

Evaporation Rate : No data available

Melting Point : No data available

Freezing Point : No data available

Boiling Point : No data available

Flash Point : No data available

Auto-ignition Temperature : No data available

Decomposition Temperature : No data available

Flammability (solid, gas) : Not applicable

Vapor Pressure : No data available

Relative Vapor Density at 20°C : No data available

Relative Density : No data available

Solubility : Water: Miscible

Partition Coefficient: N-Octanol/Water : No data available

Viscosity : No data available

9.2. Other Information

No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions

Hazardous polymerization will not occur.

10.4. Conditions to Avoid

Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials

Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products

Thermal decomposition may produce: Oxides of carbon, nitrogen, phosphorous, and sodium. . Chlorine compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity (Oral): Not classified.

Acute Toxicity (Dermal): Not classified.

Acute Toxicity (Inhalation): Not classified.

Metronidazole (443-48-1)	
LD50 Oral Rat	3 g/kg (Source: NLM_CIP)

Sodium chloride (7647-14-5)	
LD50 Oral Rat	3550 mg/kg (Species: Wistar)
LD50 Dermal Rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 Inhalation Rat	> 42 mg/l (Exposure time: 1 h Source: ECHA_API)

Phosphoric acid, disodium salt (7558-79-4)	
LD50 Oral Rat	17 g/kg
LD50 Dermal Rat	> 5000 mg/kg (50% solution)

Citric acid (77-92-9)	
LD50 Oral Rat	3 g/kg (Source: NLM_CIP)
LD50 Dermal Rat	> 2000 mg/kg (Source: EU_CLH)

Water (7732-18-5)	
LD50 Oral Rat	> 90 ml/kg (Source: FOOD_JOURN)

Skin Corrosion/Irritation: Not classified.

pH: 5 – 5.5

Serious Eye Damage/Irritation: Not classified.

pH: 5 – 5.5

Respiratory or Skin Sensitization: Not classified.

Germ Cell Mutagenicity: Not classified.

Carcinogenicity: Suspected of causing cancer (oral).

Metronidazole (443-48-1)	
IARC group	2B
National Toxicology Program (NTP) Status	Reasonably anticipated to be Human Carcinogen.
OSHA Hazard Communication Carcinogen List	In OSHA Hazard Communication Carcinogen list.

Reproductive Toxicity: oral.

Specific Target Organ Toxicity (Single Exposure): Not classified.

Specific Target Organ Toxicity (Repeated Exposure): Not classified.

Aspiration Hazard: Not classified.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Suspected of causing cancer (if swallowed). May damage fertility or the unborn child (if swallowed).

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

Metronidazole (443-48-1)	
LC50 Fish 1	> 100 mg/l (Exposure time: 96h - Species: Oncorhynchus mykiss)
EC50 - Crustacea [1]	> 1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
ErC50 (Algae)	2.17 (2.17 – 750) mg/l (Exposure time: 72h - Species: Pseudokirchneriella subcapitata)

Sodium chloride (7647-14-5)	
LC50 Fish 1	5560 (5560 – 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 - Crustacea [1]	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 Fish 2	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static] Source: EPA)
EC50 - Crustacea [2]	340.7 (340.7 – 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
NOEC Chronic Fish	252 mg/l (Species: Pimephales promelas)

Citric acid (77-92-9)	
LC50 Fish 1	1516 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus Source: OECD_SIDS)

12.2. Persistence and Degradability

Metronidazole Injection, USP	
Persistence and Degradability	Expected to be biodegradable.

Citric acid (77-92-9)	
Persistence and Degradability	Readily biodegradable in water.

12.3. Bioaccumulative Potential

Metronidazole Injection, USP	
Bioaccumulative Potential	Not expected to bioaccumulate.

Sodium chloride (7647-14-5)	
BCF Fish 1	(no bioaccumulation)

Citric acid (77-92-9)	
Partition coefficient n-octanol/water (Log Pow)	-1.72 (at 20 °C)

12.4. Mobility in Soil

Metronidazole Injection, USP	
Ecology - Soil	Adsorbs into the soil. Leaches if exposed to water.

12.5. Other Adverse Effects

Other Adverse Effects : None known.

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Waste Treatment Methods: Incineration is the preferred method for disposal of waste product. Can be landfilled, when in compliance with local regulations.

Sewage Disposal Recommendations: Do not dispose of waste into sewer. Do not empty into drains.

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional Information: Container may remain hazardous when empty. Continue to observe all precautions.

Ecology - Waste Materials: Avoid unnecessary release into the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Not regulated for transport

14.2. In Accordance with IMDG

Not regulated for transport

14.3. In Accordance with IATA

Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Metronidazole Injection, USP	
SARA Section 311/312 Hazard Classes	Health hazard - Reproductive toxicity Health hazard - Carcinogenicity

Sodium chloride (7647-14-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	

Phosphoric acid, disodium salt (7558-79-4)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
CERCLA RQ	5000 lb

Citric acid (77-92-9)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	

Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	

15.2. US State Regulations

Metronidazole (443-48-1)
U.S. - Pennsylvania - RTK (Right to Know) List
U.S. - Massachusetts - Right To Know List
U.S. - Pennsylvania - RTK (Right to Know) - Special Hazardous Substances

Phosphoric acid, disodium salt (7558-79-4)
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List
U.S. - Massachusetts - Right To Know List
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

California Proposition 65

WARNING: This product can expose you to Metronidazole, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

Chemical Name (CAS No.)	Carcinogenicity	Developmental Toxicity	Female Reproductive Toxicity	Male Reproductive Toxicity
Metronidazole (443-48-1)	X			

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 12/18/2024

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

H319	Causes serious eye irritation
H335	May cause respiratory irritation
H341	Suspected of causing genetic defects
H351	Suspected of causing cancer
H361	Suspected of damaging fertility or the unborn child
H401	Toxic to aquatic life
H412	Harmful to aquatic life with long lasting effects

Glossary of Data Source Abbreviations

ATSDR: Agency for Toxic Substances and Disease Registry (U.S. Department of Health and Human Services)
AU_WES: Australia WES
CHEMVIEW: ChemView (U.S. Environmental Protection Agency)
EC_RAR: European Commission Renewal Assessment Report
EC_SCOEL: European Commission Scientific Committee on Occupational Exposure Limits
ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals Reports
ECHA_API: European Chemicals Agency API
ECHA_RAC: ECHA Committee for Risk Assessment
EFSA: European Food Safety Authority
EPA: U.S. Environmental Protection Agency
EPA_AEGL: Acute Exposure Guideline Levels (U.S. Environmental Protection Agency)
EPA_FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act Reregistration Eligibility Decision (U.S. Environmental Protection Agency)
EPA_HPV: High Production Volume Chemicals (U.S. Environmental Protection Agency)
EPA_TRED: Risk Assessment for Tolerance Reassessment Eligibility Decision (U.S. Environmental Protection Agency)
EU_CLH: European Union Harmonised Classification and Labelling Proposal
EU_RAR: European Union Risk Assessment Report
FOOD_JOURN: Food Research Journal (1956)
IARC: The International Agency for Research on Cancer
IDLH: National Institute for Occupational Health and Safety Immediately Dangerous to Life or Health Value Profiles
IUCLID: International Uniform Chemical Information Database
JAPAN_GHS: Japan GHS Basis for Classification Data
JP_J-CHECK: Japan J-Check
KR_NIER: South Korea National Institute of Environmental Research Evaluations
NICNAS: Australia National Industrial Chemicals Notification and Assessment Scheme
NIOSH: National Institute for Occupational Health and Safety (U.S. Department of Health and Human Services)
NLM_CIP: National Library of Medicine ChemID plus database
NLM_HSDB: National Library of Medicine Hazardous Substance Data Bank
NLM_PUBMED: National Library of Medicine PubMed database
NTP: National Toxicology Program
NZ_CCID: New Zealand Chemical Classification and Information Database
OECD_EHSP: Environment, Health, and Safety Publication (Organisation for Economic Co-operation and Development)
OECD_SIDS: Screening Information Data Sets (Organisation for Economic Co-operation and Development)
WHO: World Health Organization

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)