

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

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## METRONIDAZOLUM

### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1 Product identifier

Product name:	Metronidazole Metronidazolum Metronidazol Méttronidazole Metronidazol
N° CAS:	443-48-1
N° EC:	207-136-1

#### 1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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#### 1.3 Details of the supplier of the safety data sheet

Company:	FAC SECUNDUM ARTEM NV Oostmalsebaan 1c (unit 5) 2960 Sint-Lenaarts Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

#### 1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance/mixture

##### Classification according to (EC) n° 1272/2008

Acute Tox. 4	H302
Skin Irrit. 2	H315
Eye Irrit. 2	H319
Muta. 2	H341
STOT SE 3	H335
Carc. 1B	H350

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



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Signal word(s): Danger

### Hazard statements:

H302 Harmful if swallowed.  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H341 Suspected of causing genetic defects.  
H335 May cause respiratory irritation.  
H350 May cause cancer.

### Precautionary statements:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P281 Use personal protective equipment as required.  
P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor/... if you feel unwell.  
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P501 Dispose of contents/container in accordance with local/regional/national/international regulation.

Additional applicable label elements:



### 2.3 Other hazards

None.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name: Metronidazole  
IUPAC name: 2-(2-Methyl-5-nitro-1H-imidazol-1-yl)ethanol  
Synonyms: Flagyl  
Anagiardil  
Meronidal  
N° CAS: 443-48-1  
N° EC: 207-136-1  
Molecular Formula:  $C_6H_9N_3O_3$   
Content: 99.0 per cent to 101.0 per cent (dried substance)

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

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General notes:	Consult a doctor. Show the safety data sheet to the doctor on duty.
After inhalation:	Take to fresh air. If breathing is irregular, call a doctor immediately. Only give artificial respiration if breathing stops or under medical supervision.
After skin contact:	Wash immediately with plenty of soap and water for at least 15 minutes. Remove all contaminated clothing immediately. Get medical attention if irritation develops and persists.
After eye contact:	Remove contact lenses and rinse immediately with plenty of water, including under the eyelids, for at least 15 minutes. Get medical attention.
After ingestion:	If conscious, give the victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately.

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

Not available.

### 4.3 Indication of any immediate medical attention and special treatment needed

Not available.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media: Foam, dry powder, carbon dioxide, sand, water mist.  
Containers exposed to fire: Water spray or fog.

Unsuitable extinguishing media: Direct water jet.

### 5.2 Special hazards arising from the substance/mixture

In case of fire, fumes harmful to health may be produced.

### 5.3 Advice for firefighters

Surrounding fires:	Cool containers with water to prevent decomposition of product and development of potential health hazards. Always use full fire protection. Collect water from which must not enter sewage system. Dispose of contaminated water used for extinguishing and residues in accordance with current regulations.
Protection against fire:	Helmet with visor, flame retardant clothing (jacket and trousers with straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a face mask with full face shield covering the operator or the car (self protective) in case of large amounts of smoke, a self-contained breathing apparatus (EN 137).
Hazardous combustion products:	Not available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

For exposure control and personal protective measures, see section 8.

Equip clean-up personnel with appropriate protective equipment. Ventilate area and evacuate unnecessary personnel.

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### For emergency responders

For exposure control and personal protective measures, see section 8.

### 6.2 Environmental precautions

Avoid penetration of the product into sewers, surface and groundwater. If product enters drains, notify authorities.

### 6.3 Methods and material for containment and cleaning up

Collect dry, place in a bag and keep for later disposal as waste.

Avoid raising dust. Ventilate the room and wash the place where the product has been spilled, once it has been completely removed.

### 6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling:

Avoid dispersing product into the environment.

Personal protection:

Do not eat, drink or smoke during use. Remove contaminated clothing and protective equipment before entering eating areas.

Technical protective measures:

Not available.

Handling:

Handle the product after consulting all other sections of this safety data sheet.

### 7.2 Conditions for safe storage, including any incompatibilities

Storage:

Store only in original container.

Conditions for safe storage, including any incompatibilities:

Keep container closed, in a dry, well-ventilated place.

Storage – away from:

Protect from light. Store containers away from incompatible materials, see section 10.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Not available.

### 8.2 Exposure controls

#### Appropriate engineering control

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must be CE-marked for compliance with applicable regulations. Provide an emergency shower with a viscoelastic tray.

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Hygiene measures: Handle with proper industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after finishing work.

### Individual protection measures

Eye/face protection: Protective face shields and safety goggles according to EN166.

Skin protection: Choose body protection according to the quantity and concentration of the hazardous substance in the workplace.

Hand protection: Handle with gloves. The selected protective gloves must comply with the specifications of EU Directive 89/686/EEC and the derived EN 374 standard.

Respiratory protection: Where risk assessment shows that air-purifying respirators are appropriate, use dust mask type N95 (USA) or type P1 (EN 143). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (US) or CEN (EU).

Thermal hazards: Not determined.

### Environmental exposure control

Not available.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance: White or yellowish, crystalline powder.

Odour: Odourless.

Odour threshold: Not available.

pH: Not available.

Melting/freezing point: 159 °C to 163 °C

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: Not available.

Evaporation rate: Not available.

Flammability (solid/gas): Not available.

Upper/lower flammability or explosive limits: Not available.

Vapour pressure: Not available.

Vapour density: Not available.

Relative density: Not available.

Solubility: Slightly soluble in acetone, in alcohol and in methylene chloride.

Solubility in water: Slightly soluble in water.

Partition coefficient (n-octanol/water): LowPow -0.02

Auto-ignition temperature: Not available.

Decomposition temperature: Not available.

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Viscosity: Not available.

Explosive properties: Not available.

Oxidising properties: Not available.

### 9.2 Other information

Density (25 °C): 0.652 g/ml

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

No special conditions.

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

### 10.2 Chemical stability

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

### 10.3 Possibility of hazardous reactions

Decomposition by heat may produce toxic fumes of CO, CO<sub>2</sub> and NO<sub>x</sub>.

The product has no possibility of hazardous polymerisation.

### 10.4 Conditions to avoid

Avoid any type of incorrect handling: high pressures and/or temperatures.

Direct sunlight.

### 10.5 Incompatible materials

Strong oxidising agents.

### 10.6 Hazardous decomposition products

Toxic fumes of carbon oxides (CO<sub>x</sub>) and nitrogen oxides (NO<sub>x</sub>).

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity: Oral LD<sub>50</sub> (rat): 3 000 mg/kg

Oral LD<sub>50</sub> (mouse): 3 800 mg/kg

Skin corrosion/irritation: May cause skin irritation.

Serious eye damage/irritation: May cause eye irritation.

Respiratory/skin sensitisation: Irritant to mucous membranes and upper respiratory tract.

Germ cell mutagenicity: Laboratory experiments have shown mutagenic effects.

Carcinogenicity: This product is or contains a component that has been documented as a possible carcinogen based on its IARC, ACGIH, NTP or EPA classification.

Reproductive toxicity: Not available.

Summary of evaluation of the CMR properties: Not available.

STOT-single exposure: Not available.

STOT-repeated exposure: Not available.

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Aspiration Hazard: Not available.  
Other: RTECS: NI5600000  
Signs and symptoms of exposure: Exposure may cause paraesthesia.

### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact: May cause eye irritation.  
Skin contact: Harmful if absorbed through skin. May cause skin irritation.  
Inhalation: Harmful if inhaled. May cause respiratory tract irritation.  
Ingestion: Harmful if swallowed.  
Aspiration: Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

Not available.

### 12.2 Persistence and degradability

Not available.

### 12.3 Bioaccumulative potential

Not available.

### 12.4 Mobility in soil

Not available.

### 12.5 Results of PBT and vPvB assessment

Not available.

### 12.6 Other adverse effects

Use in accordance with good working practices, avoiding dispersal of the product into the environment.  
Notify the competent authorities if the product reaches watercourses, sewers, soil or vegetation.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.  
Contaminated container: Dispose of as unused product.

## SECTION 14: TRANSPORT INFORMATION

### Transport information according to ADR/RID/IMDG/ICAO/IATA

#### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

#### 14.2 UN proper shipping name

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ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

### 14.6 Special precautions for user

Not available.

### 14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

### 14.8 Additional transport information

The product is not to be considered dangerous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

## SECTION 15: REGULATORY INFORMATION

### 15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Hazard symbol:



Harmful  
Irritant

Risk phrases:

R22 Harmful if swallowed.  
R36/37/38 Irritating to eyes, respiratory system and skin.  
R45 May cause cancer.

Safety phrases:

S23 Do not breathe dust/fume/gas/mist/vapours/spray.  
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

### 15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

## SECTION 16: OTHER INFORMATION

### 16.1 Changes since the previous version

Not applicable.

### 16.2 Abbreviations and acronyms used



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ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

### 16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

### 16.4 Method of classification in case of mixture

Not applicable.

### 16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

### 16.6 Training advisement

Not available

### 16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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### 16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

[info@magis-pharma.be](mailto:info@magis-pharma.be)

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