

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 17.03.2023

Version number 2.00 (replaces version 1.00)

Revision: 17.03.2023

1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** Metronidazole, micronized, API
- **Article number:** 4419
- **CAS Number:**
443-48-1
- **EC number:**
207-136-1
- **Registration number** The substance is exempt from REACH-registration.
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture**
Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.
- **Uses advised against** No relevant information available.
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
CAELO
Caesar & Loretz GmbH
Herderstr. 31
D-40721 Hilden
GERMANY
- **Further information obtainable from:**
E-mail: info@caelo.de
Tel.: +49210349940 (during regular opening hours)
- **Emergency telephone number:**
Poison Information Center Bonn
Venusberg-Campus 1, 53127 Bonn
Tel: +49 (0) 228-192400

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Carc. 2 H351 Suspected of causing cancer.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The substance is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS08

- **Signal word** Warning

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· Hazard statements

H351 Suspected of causing cancer.

· Precautionary statements

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/hearing 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/international regulations.

· Other hazards**· Results of PBT and vPvB assessment****· PBT:** Not applicable.**· vPvB:** Not applicable.**· Determination of endocrine-disrupting properties** Not applicable.

3 Composition/information on ingredients

· Substances**· CAS No. Description**

CAS: 443-48-1 metronidazole

· Identification number(s)**· EC number:** 207-136-1

4 First aid measures

· Description of first aid measures**· After inhalation:** Supply fresh air; consult doctor in case of complaints.**· After skin contact:** Generally the product does not irritate the skin.**· After eye contact:** Rinse opened eye for several minutes under running water.**· After swallowing:** If symptoms persist consult doctor.**· Most important symptoms and effects, both acute and delayed**

No further relevant information available.

· Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

· Extinguishing media**· Suitable extinguishing agents:**

All regular extinguishing media can be used.

Use fire extinguishing methods suitable to surrounding conditions.

· Special hazards arising from the substance or mixture

Combustible but not oxidising. In case of fire dangerous vapours/gases can be generated: Smoke gases.

· Advice for firefighters**· Protective equipment:** In case of fire wear suitable protective clothes and respiratory protection.

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· Additional information

Prevent from entering into drains. Fire residues must be disposed in accordance with official regulations.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Avoid formation of dust.

Avoid contact with the substance.

· Environmental precautions:

Do not allow to enter sewers/ surface or ground water.

Inform respective authorities in case of seepage into water course or sewage system.

· Methods and material for containment and cleaning up:

Take up dry. Clean up with water.

Dispose contaminated material as waste according to item 13.

· 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.

7 Handling and storage

· Precautions for safe handling Ensure good ventilation/exhaustion at the workplace.**· Information about fire - and explosion protection:** No special measures required.**· Conditions for safe storage, including any incompatibilities****· Storage:****· Requirements to be met by storerooms and receptacles:**

Tightly closed. Store at a dry place. At room temperature (+15°C to +25°C).

· Information about storage in one common storage facility: Not required.**· Further information about storage conditions:**

Protect from exposure to the light.

Avoid contact with air / oxygen.

· Storage class: TRHS 510: 6.1 C Combustible acutely toxic or chronic substances**· Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· Control parameters**· Ingredients with limit values that require monitoring at the workplace:** Not required.**· Additional information:** The lists valid during the making were used as basis.**· Exposure controls****· Appropriate engineering controls** No further data; see item 7.**· Individual protection measures, such as personal protective equipment****· General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

Store protective clothing separately.

· Respiratory protection: Dust protection mask.**· Hand protection** Protective gloves

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Material of gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye/face protection Safety glasses**Body protection:** Protective work clothing

9 Physical and chemical properties

Information on basic physical and chemical properties**General Information****Physical state**

Solid

Colour:

Cream coloured

Odour:

Nearly odourless

Odour threshold:

Not determined.

Melting point/freezing point:

158–160 °C

Boiling point or initial boiling point and boiling range

Undetermined.

Flammability

Product is not flammable.

Lower and upper explosion limit**Lower:**

Not determined.

Upper:

Not determined.

Flash point:

Not applicable.

Decomposition temperature:

Not determined.

pH (9.5 g/l) at 20 °C

5.8

Viscosity:**Kinematic viscosity**

Not applicable.

Dynamic:

Not applicable.

Solubility**water at 20 °C:**

9.5 g/l

Partition coefficient n-octanol/water (log value)

Not determined.

Vapour pressure:

Not applicable.

Density and/or relative density**Density:**

Not determined.

Relative density

Not determined.

Vapour density

Not applicable.

Particle characteristics

Not determined

Other information**Appearance:****Form:**

Solid

Important information on protection of health and environment, and on safety.**Auto-ignition temperature:**

Not determined.

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· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Evaporation rate	Not applicable.
· Information with regard to physical hazard classes	
· Explosives	Void
	Void
· Flammable gases	Void
	Void
· Aerosols	Void
	Void
· Oxidising gases	Void
	Void
· Gases under pressure	Void
	Void
· Flammable liquids	Void
	Void
· Flammable solids	Void
	Void
· Self-reactive substances and mixtures	Void
	Void
· Pyrophoric liquids	Void
	Void
· Pyrophoric solids	Void
	Void
· Self-heating substances and mixtures	Void
	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
	Void
· Oxidising liquids	Void
	Void
· Oxidising solids	Void
	Void
· Organic peroxides	Void
	Void
· Corrosive to metals	Void
	Void
· Desensitised explosives	Void
	Void

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.

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- **Conditions to avoid** No further relevant information available.
 - **Incompatible materials:**
 - strong oxidizing agents
 - strong bases
 - **Hazardous decomposition products:** Nitrogen oxides
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* 11 Toxicological information

- **Information on hazard classes as defined in Regulation (EC) No 1272/2008**
 - **Acute toxicity** Based on available data, the classification criteria are not met.
 - **LD/LC50 values relevant for classification:**
 - Oral LD50 3,000 mg/kg (rat)
 - **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
 - **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
 - **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
 - **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
 - **Carcinogenicity**
 - Suspected of causing cancer.
 - IARC: 2B Possibly carcinogenic to humans
 - **Reproductive toxicity** Based on available data, the classification criteria are not met.
 - **STOT-single exposure** Based on available data, the classification criteria are not met.
 - **STOT-repeated exposure** Based on available data, the classification criteria are not met.
 - **Aspiration hazard** Based on available data, the classification criteria are not met.
 - **Information on other hazards**
 - **Endocrine disrupting properties**
 - On the basis of the available data, the substance does not meet the criteria for the identification of substances having properties of interference with the endocrine system, in accordance with Article 59, paragraph 1 of the REACH Regulation and the criteria established in the Delegated Regulation (EU) 2017 / 2100 of the Commission or in Commission Regulation (EU) 2018/605.
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* 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:**
 - LC50 1,000 mg/L /48h (Daphnia magna)
- **Persistence and degradability** No further relevant information available.
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Endocrine disrupting properties**
 - Based on the available data, the substance does not meet the criteria for the identification of substances with properties affecting the endocrine system according to Article 59(1) of the REACH Regulation and the criteria of the Commission Delegated Regulation (EU) 2017/2100 or in the Commission Regulation (EU) 2018/605.
 - The product does not contain substances with endocrine disrupting properties.

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· Other adverse effects**· Remark:** Harmful to fish**· Additional ecological information:****· General notes:**

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

Danger to drinking water if even extremely small quantities leak into the ground.

Harmful to aquatic organisms

13 Disposal considerations

· Waste treatment methods**· Recommendation**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· Uncleaned packaging:**· Recommendation:** Disposal must be made according to local regulations.

* 14 Transport information

· UN number or ID number

Not subject to transport regulations.

· ADR, IMDG, IATA

not regulated

· UN proper shipping name**· ADR, IMDG, IATA**

not regulated

· Transport hazard class(es)**· ADR, ADN, IMDG, IATA****· Class**

not regulated

· Packing group**· ADR, IMDG, IATA**

not regulated

· Environmental hazards:

Not applicable.

· Special precautions for user

Not applicable.

· Maritime transport in bulk according to IMO instruments

Not applicable.

· UN "Model Regulation":not regulated

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture**· LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (ANNEX XIV)** Not listed**· REGULATION (EC) No 1907/2006 ANNEX XVII** Not listed**· DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

Substance is not listed.

· National regulations:**· Storage of hazardous substances in nonstationary vessels (TRGS 510) (Germany)**

TRHS 510: 6.1 C Combustible acutely toxic or chronic substances

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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16 Other information

The information provided is based on our current level of knowledge. This MSDS has been compiled and is exclusively for this product intended.

· **Reasons for alterations** This version replaces all old versions.

· **Date of previous version:** 17.03.2023

· **Version number of previous version:** 1.00

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

MAL-Code: Måleteknisk Arbejdshygjensk Luftbehov (Regulation for the labeling concerning inhalation hazards, Denmark)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Carc. 2: Carcinogenicity – Category 2

· * **Data compared to the previous version altered.**