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

Printing date 22.10.2021 Version number 1.00 Revision: 17.10.2021

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

- · Product identifier
- · Trade name: Metronidazole 25% with white petrolatum
- · Article number: 7290
- · 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
- · 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

Muta. 2 H341 Suspected of causing genetic defects.

Carc. 1A H350 May cause cancer.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

- · Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

Hazard pictograms



GHS08

- Signal word Danger
- · Hazard statements

H341 Suspected of causing genetic defects.

H350 May cause cancer.



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H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P103 Read carefully and follow all instructions. P201 Obtain special instructions before use. P273 Avoid release to the environment.

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.

3 Composition/information on ingredients

- **Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.
- Dangerous components:

CAS: 443-48-1 metronidazole 25.0%

EINECS: 207-136-1 Muta. 2, H341; Carc. 1A, H350; Aquatic Chronic 3, H412

- · Non-hazardous components CAS: 8009-03-8 Vaseline
- · Additional information: For the wording of the listed hazard phrases refer to section 16.

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.
- · Information for 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. (Contd. on page 3)



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

- · Handling:
- · Precautions for safe handling Ensure good ventilation/exhaustion at the workplace.
- · Information about fire and explosion protection: Keep respiratory protective device available.
- · 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.
- 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

- · Additional information about design of technical facilities: No further data; see item 7.
- Control parameters
- Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · Exposure controls
- 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.

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- · Respiratory protection: Dust protection mask.
- · Protection of hands: Protective gloves
- 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 protection: Tightly sealed goggles
 Body protection: Protective work clothing

9 Physical and chemical properties

- · Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Pasty

Colour: Cream coloured
Odour: Nearly odourless
Odour threshold: Not determined.

• pH-value at 20 °C: 6.5–7.5

· Change in condition

Melting point/freezing point: 35–40 °C Initial boiling point and boiling range: Undetermined.

• Flash point: Not applicable.

• Flammability (solid, gas): Not applicable.

Decomposition temperature: Not determined.

· **Auto-ignition temperature:** Product is not selfigniting.

• **Explosive properties:** Product does not present an explosion hazard.

· Explosion limits:

Lower:
Upper:
Not determined.
Not determined.

Vapour pressure:
Not determined.

Density:
Relative density
Vapour density
Vapour density
Evaporation rate
Not determined.
Not determined.

· Solubility in / Miscibility with

water: Fully miscible.

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· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic: Not determined. **Kinematic:** Not determined.

· Solvent content:

 VOC (EC)
 0.00 %

 Solids content:
 25.0 %

· Other information No further relevant information available.

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.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials:

strong oxidizing agents

strong bases

· Hazardous decomposition products: Nitrogen oxides

11 Toxicological information

- Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- · Primary irritant effect:
- · 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.
- · Additional toxicological information:
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity

Suspected of causing genetic defects.

· Carcinogenicity

May cause cancer.

- · 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.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.

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- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Ecotoxical 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

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · **vPvB**: Not applicable.
- · Other adverse effects No further relevant information available.

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** 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.

· Transport in bulk according to Annex II of

Marpol and the IBC Code Not applicable.

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 Conditions of restriction: 3, 28

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- · National regulations:
- · Storage of hazardous substances in 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.

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.
- Relevant phrases

H341 Suspected of causing genetic defects.

H350 May cause cancer.

H412 Harmful to aquatic life with long lasting effects.

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

ELINCS: European List of Notified Chemical Substances

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

VOC: Volatile Organic Compounds (USA, EU)

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

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

Muta. 2: Germ cell mutagenicity - Category 2

Carc. 1A: Carcinogenicity - Category 1A

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard - Category 3

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