

Metronidazole

Safety Data Sheet

637734

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Version: 3.1

Date of issue: 25/02/2015 Revision date 31/10/2018

Supersedes 04/12/2017

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

1.1. Product identifier

Product form : Substance
Substance name : Metronidazole
IUPAC name : 2-(2-methyl-5-nitro-1H-imidazol-1-yl)ethanol
EC-No. : 207-136-1
CAS-No. : 443-48-1
Product code : 637734
Formula : C₆H₉N₃O₃
Product group : Raw material

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category : Pharmaceutical industry
Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - The Netherlands
T +31(0)23-5319093
farma@duchefa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	+44 20 7188 7188	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Carcinogenicity, Category 2 H351
Specific target organ toxicity — Single exposure, Category 2 H371

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements**Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

Hazard pictograms (CLP)

:



GHS08

Signal word (CLP)

: Warning

Hazard statements (CLP)

: H351 - Suspected of causing cancer.
H371 - May cause damage to organs.

Precautionary statements (CLP)

: P202 - Do not handle until all safety precautions have been read and understood.
P260 - Do not breathe dust/fume/gas/mist/vapours/spray.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P308+P311 - IF exposed or concerned: Call a POISON CENTER or doctor.**2.3. Other hazards**

Other hazards not contributing to the classification

: None under normal conditions.

SECTION 3: Composition/information on ingredients**3.1. Substances**

Substance type

: Antibiotics

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Metronidazole	(CAS-No.) 443-48-1 (EC-No.) 207-136-1	100	Carc. 2, H351 STOT SE 2, H371

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

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.

First-aid measures after inhalation : Assure fresh air breathing.

First-aid measures after skin contact : Wash with plenty of water/....

First-aid measures after eye contact : Immediately flush eyes thoroughly with water for at least 15 minutes.

First-aid measures after ingestion : Rinse mouth. Seek medical attention immediately.

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

No additional information available

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : All extinguishing agents can be used.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Carbon oxides (CO, CO₂). Nitrogen oxides.

5.3. Advice for firefighters

Protection during firefighting : Self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid contact with skin and eyes. Evacuate unnecessary personnel.

6.1.1. For non-emergency personnel

Protective equipment : Use the personal protective equipment as indicated in chapter 8.

6.1.2. For emergency responders

Protective equipment : For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

For containment : Sweeping or shovelling without dust for disposal.

Methods for cleaning up : Clean contaminated surfaces with an excess of water.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid raising dust. Ensure good ventilation of the work station.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed. Protect from sunlight.

Incompatible products : Strong oxidizing agent.

Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

see chapter 1.2.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

No additional information available

8.2. Exposure controls**Appropriate engineering controls:**

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

Hand protection:

Wear gloves according to EN374 to protect against skin effects from powders.

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

Dustmask with filtertype P3

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 171.2 g/mol
Colour	: white to slightly yellow.
Odour	: odourless.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 159 - 163 °C
Freezing point	: No data available
Boiling point	: 406 °C
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 1.45 g/cm ³
Solubility	: Slightly soluble in water, acetone, alcohol and methylene chloride.
Log Pow	: -0.05

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Viscosity, kinematic : No data available
Viscosity, dynamic : No data available
Explosive properties : Product is not explosive.

Oxidising properties : No data available
Explosive limits : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity**10.1. Reactivity**

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

strong heating. Direct sunlight. Keep away from sources of ignition - No smoking.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition productsCarbon oxides (CO, CO₂). Nitrogen oxides.**SECTION 11: Toxicological information****11.1. Information on toxicological effects**

Acute toxicity : Not classified

Metronidazole (443-48-1)	
LD50 oral rat	3000 mg/kg

Skin corrosion/irritation : Not classified
Serious eye damage/irritation : Not classified
Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Reported effects of mutagenesis (Inconclusive data)
Carcinogenicity : Suspected of causing cancer.

Reproductive toxicity : Not classified
STOT-single exposure : May cause damage to organs.
STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

IARC group : 2B

SECTION 12: Ecological information**12.1. Toxicity**

Ecology - water : Not harmful to fish.

Metronidazole (443-48-1)	
LC50 fish 1	> 100 mg/l
LC50 fish 2	> 100 mg/l
EC50 Daphnia 1	> 1000 mg/l
NOEC (acute)	> 500 mg/l

12.2. Persistence and degradability

Metronidazole (443-48-1)	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Metronidazole (443-48-1)	
Log Pow	-0.05
Bioaccumulative potential	Low bioaccumulation potential.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Other adverse effects : None known.

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Regional legislation (waste) : Disposal must be done according to official regulations.

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
Not applicable	Not applicable
14.2. UN proper shipping name	
Not applicable	Not applicable
14.3. Transport hazard class(es)	
Not applicable	Not applicable
Not applicable	Not applicable
14.4. Packing group	
Not applicable	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

14.6. Special precautions for user**- Overland transport**

No data available

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- Air transport

No data available

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****15.1.1. EU-Regulations**

No REACH Annex XVII restrictions

Metronidazole is not on the REACH Candidate List

Metronidazole is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

2.2	Hazard statements (CLP)	Modified	Fixed wrong hazard- and precautionary statements, they differed from actual product labelling.
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Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Data sources

: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. EP.

Full text of H- and EUH-statements:

Carc. 2	Carcinogenicity, Category 2
STOT SE 2	Specific target organ toxicity — Single exposure, Category 2
H351	Suspected of causing cancer.
H371	May cause damage to organs.

SDS EU (REACH Annex II) Version 2018

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