

Safety Data Sheet
according to Regulation (EC) No. 1907/2006 (REACH)

FIPHARMA

Trade name : Metronidazole Micronized
Revision date : 16-08-2019
Print date : 21-11-2019

Version (Revision) : 1.3.0 (1.2.13)

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

1.1 Product identifier

Metronidazole Micronized (1998)
Metronidazole ; CAS No. : 443-48-1 ; EC No. : 207-136-1

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

No information available.

1.3 Details of the supplier of the safety data sheet

Supplier (manufacturer/importer/only representative/downstream user/distributor)

Ofipharma B.V.

Street : Heembadweg 5

Postal code/city : 9561 CZ Ter Apel

Telephone : +31 599 745 390

Telefax : +31 599 582 734

1.4 Emergency telephone number

+31 599 583 433

Telefoon voor professionele hulpverleners: NVIC + (0)30 - 274 88 88. Uitsluitend bestemd om professionele hulpverleners te informeren bij acute vergiftigingen.

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

Carc. 2 ; H351 - Carcinogenicity : Category 2 ; Suspected of causing cancer.

2.2 Label elements

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

Hazard pictograms



Health hazard (GHS08)

Signal word

Warning

Hazard statements

H351 Suspected of causing cancer.

Precautionary statements

P201 Obtain special instructions before use.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P308+P313 IF exposed or concerned: Get medical advice/attention.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations

2.3 Other hazards

None

SECTION 3: Composition/information on ingredients

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3.1 Substances

Substance name : Metronidazole
EC No. : 207-136-1
CAS No. : 443-48-1
Purity : 100 % [mass]

SECTION 4: First aid measures

4.1 Description of first aid measures

No special measures are necessary.

4.2 Most important symptoms and effects, both acute and delayed

No information available.

4.3 Indication of any immediate medical attention and special treatment needed

None

SECTION 5: Firefighting measures

5.1 Extinguishing media

None

5.2 Special hazards arising from the substance or mixture

None

5.3 Advice for firefighters

None

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

None

6.2 Environmental precautions

None

6.3 Methods and material for containment and cleaning up

None

6.4 Reference to other sections

None

SECTION 7: Handling and storage

7.1 Precautions for safe handling

None

7.2 Conditions for safe storage, including any incompatibilities

Hints on joint storage

Storage class (TRGS 510) : 13

7.3 Specific end use(s)

None

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

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None

8.2 Exposure controls

No special measures are necessary.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : solid

Colour : Light yellowish.

Odour : No data available

Safety relevant basis data

Physical state :		Powder
Melting point/melting range :	(1013 hPa)	159 - 161 °C
Freezing point :	(1013 hPa)	No data available
Initial boiling point and boiling range :	(1013 hPa)	No data available
Flash point :		No data available
Ignition temperature :		No data available
Lower explosion limit :		No data available
Upper explosion limit :		No data available
Lower explosion limit :		No data available
Upper explosion limit :		No data available
Density :	(20 °C)	No data available
Relative density :	(20 °C)	No data available
Water solubility :	(20 °C)	No data available
Water solubility :	(20 °C)	No data available
pH :		No data available
Cinematic viscosity :	(40 °C)	No data available
Relative vapour density :	(20 °C)	No data available
Evaporation rate :		No data available
Flammable solids :	No data available.	
Oxidising solids :	No data available.	

9.2 Other information

None

SECTION 10: Stability and reactivity

10.1 Reactivity

No information available.

10.2 Chemical stability

No information available.

10.3 Possibility of hazardous reactions

No information available.

10.4 Conditions to avoid

No information available.

10.5 Incompatible materials

No information available.

10.6 Hazardous decomposition products

No information available.

SECTION 11: Toxicological information

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11.1 Information on toxicological effects

Acute effects

Acute oral toxicity

Parameter :	LD50
Exposure route :	Oral
Species :	Rat
Effective dose :	3000 mg/kg
Parameter :	LD50 (Metronidazole ; CAS No. : 443-48-1)
Exposure route :	Oral
Species :	Rat
Effective dose :	3000 mg/kg

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity

Acute (short-term) algae toxicity

Parameter :	EC50
Species :	Daphnia magna (Big water flea)
Effective dose :	1000 mg/l
Exposure time :	48 h
Parameter :	EC50 (Metronidazole ; CAS No. : 443-48-1)
Species :	Daphnia magna (Big water flea)
Effective dose :	1000 mg/l
Exposure time :	48 h

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

No information available.

12.6 Other adverse effects

No information available.

12.7 Additional ecotoxicological information

None

SECTION 13: Disposal considerations

13.1 Waste treatment methods

No information available.

SECTION 14: Transport information

14.1 UN number

No dangerous good in sense of these transport regulations.

14.2 UN proper shipping name

No dangerous good in sense of these transport regulations.

14.3 Transport hazard class(es)

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No dangerous good in sense of these transport regulations.

14.4 Packing group

No dangerous good in sense of these transport regulations.

14.5 Environmental hazards

No dangerous good in sense of these transport regulations.

14.6 Special precautions for user

None

SECTION 15: Regulatory information

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

EU legislation

Authorisations and/or restrictions on use

Restrictions on use

Use restriction according to REACH annex XVII, no. : 3

National regulations

Water hazard class (WGK)

Class : nwg (Non-hazardous to water)

15.2 Chemical safety assessment

No information available.

SECTION 16: Other information

16.1 Indication of changes

02. Labelling according to Regulation (EC) No. 1272/2008 [CLP] · 15. Restrictions on use · 15. Water hazard class (WGK)

16.2 Abbreviations and acronyms

None

16.3 Key literature references and sources for data

None

16.4 Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

No information available.

16.4 Relevant H- and EUH-phrases (Number and full text)

None

16.5 Training advice

None

16.6 Additional information

None

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.