

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



**Trade name :** Metronidazole  
**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 (1926)  
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

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