

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

RONIDAZOLUM

EN

FORM-06-14-01 (V00)

Page 1/9

Publication: 09/11/2022

Revision: XX/XX/XXXX

Version: 00



SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

| | |
|---------------|--|
| Product name: | Ronidazole Ronidazolum Ronidazole Ronidazole Ronidazol |
| N° CAS: | 7681-76-7 |
| N° EC: | 231-675-1 |

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

| | |
|------------------|--|
| Identified uses: | Active Pharmaceutical Ingredient or Excipient. |
|------------------|--|

1.3 Details of the supplier of the safety data sheet

| | |
|------------|---|
| Company: | FAC SECUNDUM ARTEM NV Oostmalsebaan 1c (unit 5) 2960 Sint-Lenaarts Belgium |
| Telephone: | (+32) (0)3 457 11 76 |
| Email: | info@magis-pharma.be |
| Web page: | www.magis-pharma.be |

1.4 Emergency telephone number

| | | |
|----------------------------|-------------------------|--------------------------|
| Public utility foundation: | Belgisch Antigifcentrum | Centre Antipoisons Belge |
| Telephone: | (+32) (0)70 245 245 | (Service 24/7) |
| Web page: | www.antigifcentrum.be | www.centreantipoisons.be |

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

The substance is not classified according to Regulation (EC) 1272/2008 (CLP).

2.2 Label elements

Labelling according to (EC) n° 1272/2008

| | |
|---------------------------------------|--|
| Hazard pictogram(s): | Not applicable. |
| Signal word(s): | Not applicable. |
| Hazard statements: | Not applicable. |
| Precautionary statements: | |
| P262 | Do not get in eyes, on skin, or on clothing. |
| P280 | Wear protective gloves/protective clothing/eye protection/face protection. |
| Additional applicable label elements: | Not applicable. |

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

RONIDAZOLUM

EN

FORM-06-14-01 (V00)

Page 2/9

Publication: 09/11/2022

Revision: XX/XX/XXXX

Version: 00



2.3 Other hazards

None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

| | |
|--------------------|--|
| Product name: | Ronidazole |
| IUPAC name: | (1-methyl-5-nitroimidazol-2-yl)methyl carbamate |
| Synonyms: | Ridzol Ridazole |
| N° CAS: | 7681-76-7 |
| N° EC: | 231-675-1 |
| Molecular Formula: | $C_6H_8N_4O_4$ |
| Content: | It contains not less than 98.5% and not more than 101.0% of $C_6H_8N_4O_4$, calculated with reference to the anhydrous substance. |

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

| | |
|---------------------|--|
| General notes: | Consult a doctor. Show safety data sheet to doctor on duty. |
| After inhalation: | Remove to fresh air. If breathing is irregular, call a doctor immediately. Only give artificial respiration if breathing stops or under medical supervision. |
| After skin contact: | Wash immediately with plenty of soap and water for at least 15 minutes. Remove all contaminated clothing immediately. Get medical attention if irritation develops and persists. |
| After eye contact: | Remove contact lenses and rinse immediately with plenty of water, including under eyelids, for at least 15 minutes. Get medical attention. |
| After ingestion: | If conscious, give victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately. |

4.2 Most important symptoms and effects, both acute and delayed

There are no known acute or delayed effects from exposure to the product.

4.3 Indication of any immediate medical attention and special treatment needed

In cases of doubt, or when symptoms of discomfort persist, seek medical attention. Never administer anything by mouth to an unconscious person.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

| | |
|---------------------------------|---|
| Suitable extinguishing media: | Foam, dry powder, carbon dioxide, sand, water fog. Nearby fires (fire-exposed containers): Water spray or water fog. |
| Unsuitable extinguishing media: | Direct water jet. |

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

RONIDAZOLUM

EN

FORM-06-14-01 (V00)

Page 3/9

Publication: 09/11/2022

Revision: XX/XX/XXXX

Version: 00



5.2 Special hazards arising from the substance/mixture

Avoid breathing combustion product.

5.3 Advice for firefighters

Surrounding fires:

Cool containers with water to prevent decomposition of product and development of health hazards. Always use full fire protection. Collect water from entering sewage system. Dispose of contaminated water used to extinguish and the remains of the second in accordance with current regulations.

Protection against fire:

Helmet with visor, fireproof clothing (jacket and trousers with straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the entire face of the operator or self (self protective) in the case of large quantities of smoke, a self-contained breathing apparatus (EN 137).

Hazardous combustion products:

Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Not available.

For emergency responders

If vapours from breathing or dust are released into the air, wear respiratory protection. These guidelines are only valid for emergency workers and emergency actions.

6.2 Environmental precautions

Avoid penetration of products into sewers, surface water, groundwater.

6.3 Methods and material for containment and cleaning up

Smother with earth or inert material. Collect most of the material and remove the residue with water jets, follow the recommendations in section 13.

6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Smoking, eating and drinking must be prohibited in the area of application.

Personal protection:

Not available.

Technical protective measures:

Not available.

Handling:

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Not available.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 4/9

Publication: 09/11/2022

Revision: XX/XX/XXXX

Version: 00



RONIDAZOLUM

Conditions for safe storage, including any incompatibilities:

Storage – away from:

The product does not require special storage measures. Store containers in a cool, dry and well-ventilated place.

Keep away from naked flames, sparks and sources of ignition. Protected from light.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must be CE-marked for compliance with applicable regulations. Provide an emergency shower with a visco-elastic tray.

Hygiene measures: Handle with proper industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after finishing work.

Individual protection measures

Eye/face protection: Protective face shields and safety goggles according to EN166.

Skin protection: Choose body protection according to the quantity and concentration of the hazardous substance in the workplace.

Hand protection: Handle with gloves.
The selected protective gloves must comply with the specifications of EU Directive 89/686/EEC and the derived EN 374 standard.

Respiratory protection: Where risk assessment shows that air-purifying respirators are appropriate, use dust mask type N95 (USA) or type P1 (EN 143). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (US) or CEN (EU).

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: A white to yellowish brown powder.

Odour: Odourless or almost odourless.

Odour threshold: Not available.

pH: Not available.

Melting/freezing point: About 167 °C

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 5/9

Publication: 09/11/2022

Revision: XX/XX/XXXX

Version: 00



RONIDAZOLUM

| | |
|---|---|
| Initial boiling point: | Not available. |
| Boiling range: | Not available. |
| Flash point: | Not available. |
| Evaporation rate: | Not available. |
| Flammability (solid/gas): | Not available. |
| Upper/lower flammability or explosive limits: | Not available. |
| Vapour pressure: | Not available. |
| Vapour density: | Not available. |
| Relative density: | Not available. |
| Solubility: | Slightly soluble in chloroform and in ethanol (96%). Very slightly soluble in ether. |
| Solubility in water: | Slightly soluble in water. |
| Partition coefficient (n-octanol/water): | Not available. |
| Auto-ignition temperature: | Not available. |
| Decomposition temperature: | Not available. |
| Viscosity: | Not available. |
| Explosive properties: | Not available. |
| Oxidising properties: | Not available. |

9.2 Other information

| | |
|-------------------|--------------|
| Molecular weight: | 200.15 g/mol |
| Density (20 °C): | 0.348 g/mL |

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No special conditions.

10.2 Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

The product does not present the possibility of hazardous reactions.

10.4 Conditions to avoid

None in particular.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Not available.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

RONIDAZOLUM

EN

FORM-06-14-01 (V00)

Page 6/9

Publication: 09/11/2022

Revision: XX/XX/XXXX

Version: 00



SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

| | | |
|--|--|------------|
| Acute toxicity: | Acute oral toxicity (LD ₅₀ , rat): | 3400 mg/kg |
| | Acute intraperitoneal toxicity (LD ₅₀ , rat): | 1500 mg/kg |
| Skin corrosion/irritation: | Not available. | |
| Serious eye damage/irritation: | Not available. | |
| Respiratory/skin sensitisation: | Not available. | |
| Germ cell mutagenicity: | Not available. | |
| Carcinogenicity: | The IARC working group evaluated the biological effects of talc and concluded, due to in vivo and in vitro studies, that there is insufficient evidence of carcinogenicity or genetic toxicity in both animal and human experiments. | |
| Reproductive toxicity: | Not available. | |
| Summary of evaluation of the CMR properties: | Not available. | |
| STOT-single exposure: | Not available. | |
| STOT-repeated exposure: | Not available. | |
| Aspiration Hazard: | Not available. | |
| Other: | Not available. | |

11.2 Additional information on potential adverse human health effects and symptoms

| | |
|---------------|----------------|
| Eye contact: | Not available. |
| Skin contact: | Not available. |
| Inhalation: | Not available. |
| Ingestion: | Not available. |
| Aspiration: | Not available. |

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

According to available data, the product does not contain PBT or vPvB substances in concentrations higher than 0.10 %.

12.6 Other adverse effects

Use in accordance with good laboratory practice, avoid dispersal into the environment. Inform the competent authorities if the product contaminates ground water, sewage, soil or vegetation.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

RONIDAZOLUM

EN

FORM-06-14-01 (V00)

Page 7/9

Publication: 09/11/2022

Revision: XX/XX/XXXX

Version: 00



SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated container

Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

14.6 Special precautions for user

It is not dangerous in transport.

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

Not available.

14.8 Additional transport information

The product is not to be considered dangerous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not applicable.

Risk phrases: Not applicable.

Safety phrases: S24/25 Avoid contact with skin and eyes.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

RONIDAZOLUM

EN

FORM-06-14-01 (V00)

Page 8/9

Publication: 09/11/2022

Revision: XX/XX/XXXX

Version: 00



15.2 Chemical safety assessment

A chemical safety assessment of the product has not been carried out.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

| | |
|--------------|---|
| ADR: | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| CAS: | Chemical Abstracts Service (division of the American Chemical Society) |
| EC (number): | European Community (number) |
| IATA: | International Air Transport Association |
| ICAO: | International Civil Aviation Organization |
| IMDG: | International Maritime Code for Dangerous Goods |
| IUPAC: | International Union of Pure and Applied Chemistry |
| PBT: | Persistent, Bioaccumulative and Toxic substance |
| RID: | Regulations Concerning the International Transport of Dangerous Goods by Rail |
| STOT: | Specific Target Organ Toxicity |
| UN (number): | United Nations (number) |
| vPvB: | very Persistent and very Bioaccumulative |

16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FSA NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

RONIDAZOLUM

EN

FORM-06-14-01 (V00)

Page 9/9

Publication: 09/11/2022

Revision: XX/XX/XXXX

Version: 00



regarding its accuracy or correctness. FSA NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

info@magis-pharma.be