

# Material Safety Data Sheet

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

## OMEPRAZOLUM

EN

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Revision: XX/XX/XXXX

Version: 00



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

#### 1.1 Product identifier

Product name:	Omeprazole Omeprazolum Omeprazol Oméprazole Omeprazol
N° CAS:	73590-58-6
N° EC:	615-996-8

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

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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#### 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

Skin Irrit. 2	H315
Eye Irrit. 2	H319
STOT SE 3	H335

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H315 Causes skin irritation.

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H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
Precautionary statements:	
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash hands thoroughly after handling.
P280	Wear protective gloves/protective clothing/ eye protection/face protection.
P362+364	Take off contaminated clothing and wash it before reuse.
Additional applicable label elements:	Not applicable.

### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Omeprazole
IUPAC name:	5-Methoxy-2-[(RS)-[(4-methoxy-3,5-dimethylpyridin-2-yl)methyl]sulfinyl]-1H-benzimidazole.
Synonyms:	Prilosec Losec Esomeprazole
N° CAS:	73590-58-6
N° EC:	615-996-8
Molecular Formula:	C <sub>17</sub> H <sub>19</sub> N <sub>3</sub> O <sub>3</sub> S
Content:	99.0 per cent to 101.0 per cent (dried substance)

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

After inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
After skin contact:	In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.
After eye contact:	Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. WARM water MUST be used. Get medical attention.
After ingestion:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

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

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Causes serious eye irritation. Material may be irritating to the mucous membranes and upper respiratory tract. May be harmful by inhalation, ingestion, or skin absorption. May cause respiratory irritation. To the best of our knowledge, the toxicological properties have not been thoroughly investigated.

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

Not available.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media:	Water spray, carbon dioxide, dry powder. Fight larger fires with water spray or alcohol. Use fire extinguishing methods suitable to surrounding conditions.
Unsuitable extinguishing media:	Do not use heavy or solid water stream.

### 5.2 Special hazards arising from the substance/mixture

Not available.

### 5.3 Advice for firefighters

Surrounding fires:	Use water spray or fog for cooling exposed containers.
Protection against fire:	Do not enter fire area without proper protective equipment including respiratory protection.
Hazardous combustion products:	Incomplete combustion will generate poisonous carbon monoxide, carbon dioxide and other toxic gases.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Ensure adequate ventilation. Wear protective clothing. Avoid formation of dust. Keep away from ignition sources.

#### For emergency responders

Ensure adequate ventilation. Wear protective clothing. Avoid formation of dust. Keep away from ignition sources.

### 6.2 Environmental precautions

Not available.

### 6.3 Methods and material for containment and cleaning up

Not available.

### 6.4 Reference to other sections

Not available.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling:	Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume
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Personal protection:	hood. Ground all equipment containing material. Keep away from incompatibles such as oxidising agents. Do not ingest. Do not breathe dust. If ingested, seek medical advice immediately and show the container or the label.
Technical protective measures:	Not available.
Handling:	Not available.

### 7.2 Conditions for safe storage, including any incompatibilities

Storage:	In an airtight container.
Conditions for safe storage, including any incompatibilities:	Store at a temperature of 2 °C to 8°C. Keep away from incompatibles such as oxidising agents.
Storage – away from:	Store protected from light. Keep away from heat and sources of ignition.

### 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

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

#### Individual protection measures

Eye/face protection:	Safety glasses. In case of a large spill: splash goggles.
Skin protection:	Lab coat. In case of a large spill: full suit, boots. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.
Hand protection:	Gloves (impervious, chemical-resistant). In case of a large spill: gloves.
Respiratory protection:	Dust respirator. Be sure to use an approved/certified respirator or equivalent. In case of a large spill: dust respirator. A self contained breathing apparatus should be used to avoid inhalation of the product.
Thermal hazards:	Not determined.

#### Environmental exposure control

Not available.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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### 9.1 Information on basic physical and chemical properties

Appearance:	White or almost white powder; crystalline.
Odour:	Not available.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	150 °C – 160 °C
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:	Sparingly soluble in ethanol (96%). Freely soluble in methylene chloride and in chloroform. Soluble in methanol and in dilute solutions of alkali hydroxides.
Solubility in water:	Very 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

Water/oil dist. coeff.: The product is more soluble in oil:  $\log(\text{oil/water}) = 2.2$

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Special remarks on reactivity: Moisture sensitive.

### 10.2 Chemical stability

The product is stable. Polymerisation: Will not occur.

### 10.3 Possibility of hazardous reactions

Not available.

### 10.4 Conditions to avoid

Conditions of instability: Elevated temperatures, moisture, incompatible materials.

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### 10.5 Incompatible materials

Reactive with oxidising agents.

### 10.6 Hazardous decomposition products

Carbon dioxide, carbon monoxide, nitrogen oxides, sulfur oxides.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	Oral LD <sub>50</sub> (rat): 2 210 mg/kg Intraperitoneal LD <sub>50</sub> (rat): > 100 mg/kg Subcutaneous LD <sub>50</sub> (rat): > 100 mg/kg
Skin corrosion/irritation:	Slightly hazardous in case of skin contact (irritant).
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
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:	<u>Chronic effect on humans:</u> May cause damage to the following organs: gastrointestinal tract. May cause adverse reproductive effects based on animal data. May affect genetic material. May cross the placenta.

### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Dust may cause eye irritation.
Skin contact:	May cause skin irritation.
Inhalation:	Hazardous in case of inhalation (lung irritant). Dust may cause respiratory tract irritation.
Ingestion:	Slightly hazardous in case of ingestion. May cause digestive tract irritation with nausea, vomiting, hyper motility, and diarrhoea. May also affect: blood (Eosinophilia, Normocytic anaemia), metabolism, brain, behaviour (ataxia, convulsions, sedation, change in motor activity, decreased activity), respiration (dyspnoea, coughing, decreased respiration), liver (jaundice, hepatitis), immune system, urinary system/kidneys, and cause musculoskeletal effects.
Aspiration:	Not available.

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### SECTION 12: ECOLOGICAL INFORMATION

#### 12.1 Toxicity

Not available.

#### 12.2 Persistence and degradability

Products of biodegradation: Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the products of biodegradation: The product itself and its products of degradation are not toxic.

#### 12.3 Bioaccumulative potential

Not available.

#### 12.4 Mobility in soil

Not available.

#### 12.5 Results of PBT and vPvB assessment

Not available.

#### 12.6 Other adverse effects

Not available.

### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

### 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) : Not classified.

#### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

#### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

#### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

#### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

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### 14.6 Special precautions for user

Not available.

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

Not available.

### 14.8 Additional transport information

Not regulated as a dangerous good.

## SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Irritant

Risk phrases:

R36/37/38 Irritating to eyes, respiratory system and skin.

Safety phrases:

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S36 Wear suitable protective clothing.

### 15.2 Chemical safety assessment

Not available.

## 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



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### 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.

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### 16.8 Department issuing MSDS

Quality Department

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