

Safety data sheet

According to 1907/2006/ EEC/ Article 31

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Printing date 21.07.2014

Revision: 21.07.2014

Version number 6

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

- Product identifier
- Trade name: Omeprazole sodium
Omeprazolium natricum
- Article number: 104056
- CAS Number:
95510-70-6
- Relevant identified uses of the substance or mixture and uses advised against
No further relevant information available.
- Application of the substance / the mixture Pharma Active ingredients
- Details of the supplier of the safety data sheet
- Manufacturer/Supplier:
Fagron UK Ltd
4B Coquet St,
Newcastle upon Tyne
England NE1 2QB
- Further information obtainable from: Tel.: +44 (0) 845 652 2525
- Emergency telephone number:
Emergency response telephone number:
+44 (0) 845 652 2525

2 Hazards identification

- Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008



GHS07

- | | |
|---------------|---|
| Skin Irrit. 2 | H315 Causes skin irritation. |
| Eye Irrit. 2 | H319 Causes serious eye irritation. |
| Skin Sens. 1 | H317 May cause an allergic skin reaction. |
| STOT SE 3 | H335 May cause respiratory irritation. |

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

- Classification according to Directive 67/548/EEC or Directive 1999/45/EC



Xi; Irritant

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



Xi; Sensitising

R43: May cause sensitisation by skin contact.

R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

- Information concerning particular hazards for human and environment: Not applicable.

- Label elements

- Labelling according to Regulation (EC) No 1272/2008

The substance is classified and labelled according to the CLP regulation.

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- Hazard pictograms GHS07
- Signal word Warning
- Hazard statements
 - H315 Causes skin irritation.
 - H319 Causes serious eye irritation.
 - H317 May cause an allergic skin reaction.
 - H335 May cause respiratory irritation.
 - H412 Harmful to aquatic life with long lasting effects.
- Precautionary statements
 - P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 - P280 Wear protective gloves/protective clothing/eye protection/face protection.
 - P321 Specific treatment (see on this label).
 - P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 - P362 Take off contaminated clothing.
 - P405 Store locked up.
- Other hazards
- Results of PBT and vPvB assessment
 - PBT: Not applicable.
 - vPvB: Not applicable.

3 Composition/information on ingredients

- Chemical characterization: Substances
- CAS No. Description
 - 95510-70-6 Omeprazole sodium
 - Omeprazolium natricum
- Identification number(s) -

4 First aid measures

- Description of first aid measures
- After inhalation:
 - Supply fresh air and to be sure call for a doctor.
 - In case of unconsciousness place patient stably in side position for transportation.
- After skin contact: Immediately wash with water and soap and rinse thoroughly.
- After eye contact:
 - Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- After swallowing: Rinse out mouth and then drink plenty of water. Consult a doctor.
- Information for doctor:
 - Most important symptoms and effects, both acute and delayed No further relevant information available.
 - Indication of any immediate medical attention and special treatment needed
 - No further relevant information available.

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5 Firefighting measures

- Extinguishing media
- Suitable extinguishing agents:
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- Special hazards arising from the substance or mixture No further relevant information available.
- Advice for firefighters
- Protective equipment: No special measures required.

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures Not required.
- Environmental precautions:
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
- Methods and material for containment and cleaning up: Ensure adequate ventilation.
- Reference to other sections
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- Handling:
· Precautions for safe handling No special precautions are necessary if used correctly.
- Information about fire - and explosion protection: No special measures required.
- Conditions for safe storage, including any incompatibilities
- Storage:
· Requirements to be met by storerooms and receptacles: No special requirements.
- Information about storage in one common storage facility: Not required.
- Further information about storage conditions: Store in cool, dry conditions in well sealed receptacles.
- Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- Additional information about design of technical facilities: No further data; see item 7.
- Control parameters
- Ingredients with limit values that require monitoring at the workplace: Not required.
- Additional information: The lists valid during the making were used as basis.
- Exposure controls
- Personal protective equipment:
- General protective and hygienic measures:
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing

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Wash hands before breaks and at the end of work.

· Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

· Penetration time of glove material

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:



Tightly sealed goggles

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form: Wettable powder

Colour: White

· Odour: Characteristic

· Odour threshold: Not determined.

· pH-value: Not determined.

· Change in condition

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined.

· Flash point: Not applicable.

· Flammability (solid, gaseous): Not applicable.

· Ignition temperature:

Decomposition temperature: Not determined.

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· Self-igniting:	Not determined.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits: Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not determined.
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with water:	Not determined.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity: Dynamic:	Not determined.
Kinematic:	Not determined.
· Other information	No further relevant information available.

10 Stability and reactivity

- Reactivity
- Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- Possibility of hazardous reactions No dangerous reactions known.
- Conditions to avoid No further relevant information available.
- Incompatible materials: No further relevant information available.
- Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

- Information on toxicological effects
- Acute toxicity:

· LD/LC50 values relevant for classification:

Oral	LD50	2210 mg/kg (rat)
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- Primary irritant effect:
 - on the skin: Irritant to skin and mucous membranes.
 - on the eye: Irritating effect.
- Sensitization: Sensitization possible through skin contact.

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12 Ecological information

- Toxicity
- Aquatic toxicity: No further relevant information available.
- Persistence and degradability No further relevant information available.
- Behaviour in environmental systems:
- Bioaccumulative potential No further relevant information available.
- Mobility in soil No further relevant information available.
- Ecotoxicological effects:
- Remark: Harmful to fish
- Additional ecological information:
- General notes:
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
Harmful to aquatic organisms
- Results of PBT and vPvB assessment
- PBT: Not applicable.
- vPvB: Not applicable.
- Other adverse effects No further relevant information available.

13 Disposal considerations

- Waste treatment methods
- Recommendation
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- Uncleaned packaging:
- Recommendation: Disposal must be made according to official regulations.

14 Transport information

- | | |
|------------------------------|------|
| · UN-Number | |
| · ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | - |
| · ADR, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | No |

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- | | |
|---|-----------------|
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | - |

15 Regulatory information

- Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- Department issuing MSDS:
Fagron UK
Quality Assurance
- Contact: kathryn.mason@fagron.co.uk
- Abbreviations and acronyms:
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
- * Data compared to the previous version altered.

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