

# Safety data sheet

according to 1907/2006/EC, Article 31

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Printing date 06/25/2014

Revision: 06/25/2014

Version number 4

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

- Product identifier
- Trade name: Ondansetron Base
- Article number: 194249
- 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  
2400 Pilot Knob Road  
St. Paul, MN 55120  
[www.fagron.us](http://www.fagron.us)
- Further information obtainable from:  
Tel: 800-423-6967  
Fax: 800-339-1596
- Emergency telephone number: 800-423-6967

## 2 Hazards identification

- Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008  
The substance is not classified according to the CLP regulation.
- Classification according to Directive 67/548/EEC or Directive 1999/45/EC Not applicable.
- Information concerning particular hazards for human and environment: Not applicable.
- Label elements
- Labelling according to Regulation (EC) No 1272/2008 Void
- Hazard pictograms Void
- Signal word Void
- Hazard statements Void
- 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  
1,2,3,9-Tetrahydro-9-methyl-3-[(2-methyl-1H-imidazol-1-yl)  
methyl]-4H-carbazol-4-one
- Identification number(s) -

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## 4 First aid measures

- Description of first aid measures
- General information:  
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
- After inhalation:  
Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.  
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.
- After swallowing: Call for a doctor immediately.
- 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.

## 5 Firefighting measures

- Extinguishing media
- Suitable extinguishing agents:  
CO<sub>2</sub>, 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: Mouth respiratory protective device.

## 6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures Not required.
- Environmental precautions: No special measures required.
- Methods and material for containment and cleaning up:  
Dispose contaminated material as waste according to item 13.  
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  
Thorough dedusting.  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of dust.

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- 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.
  - 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 through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- Eye protection: Not required.

## 9 Physical and chemical properties

- Information on basic physical and chemical properties
- General Information
- Appearance:
  - Form: Solid
  - Colour: Not determined.
- Odour: Characteristic

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· Odour threshold:	Not determined.
· pH-value:	Not applicable.
· Change in condition Melting point/Melting range:	231-232 °C (448-450 °F)
Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Product is not flammable.
· Ignition temperature:	
Decomposition temperature:	Not determined.
· 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 applicable.
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with water:	Not determined.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity: Dynamic:	Not applicable.
Kinematic:	Not applicable.
· 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.

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## 11 Toxicological information

- Information on toxicological effects
- Acute toxicity:
- Primary irritant effect:
  - on the skin: No irritant effect.
  - on the eye: May have an irritating effect.
- Sensitization: No sensitizing effects known.

## 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.
- 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 |

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- |   |                 |
|---|-----------------|
| · Environmental hazards:  |                 |
| · Marine pollutant:   | No              |
| · 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 US

Quality Assurance

- Contact: [martin.erickson@fagron.us](mailto:martin.erickson@fagron.us)

- Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organization

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)

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