

Safety data sheet

according to 1907/2006/EC, Article 31

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Printing date 07/24/2014

Revision: 07/24/2014

Version number 6

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

- Product identifier
- Trade name: Tolperisone HCL
- Article number:
104041
701550
- CAS Number:
3644-61-9
- EC number:
222-876-5
- 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
- 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



GHS07

Acute Tox. 4 H302 Harmful if swallowed.
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2A H319 Causes serious eye irritation.
STOT SE 3 H335 May cause respiratory irritation.

- 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
The substance is classified and labelled according to the CLP regulation.
- Hazard pictograms GHS07
- Signal word Warning
- Hazard statements
H302 Harmful if swallowed.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

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- 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
 - 3644-61-9 Tolperisone HCL
- Identification number(s)
- EC number: 222-876-5

4 First aid measures

- Description of first aid measures
- After inhalation: Supply fresh air; consult doctor in case of complaints.
- After skin contact: Seek medical treatment.
- After eye contact: Rinse opened eye for several minutes under running water.
- After swallowing: Seek medical treatment.
- 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:
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- Special hazards arising from the substance or mixture
Formation of toxic gases is possible during heating or in case of fire.
Hydrogen chloride (HCl)
Carbon monoxide (CO)
Sulphur dioxide (SO₂)
- Advice for firefighters
- Protective equipment: Wear self-contained respiratory protective device.

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6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures
Wear protective equipment. Keep unprotected persons away.
Ensure adequate ventilation
- Environmental precautions:
Damp down dust with water spray.
Do not allow to enter sewers/ surface or ground water.
- Methods and material for containment and cleaning up: Pick up mechanically.
- 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
Keep receptacles tightly sealed.
Store in cool, dry place in tightly closed receptacles.
- 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:
Store away from oxidizing agents.
Store away from foodstuffs.
- Further information about storage conditions:
Store receptacle in a well ventilated area.
Protect from humidity and water.
- 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:
The usual precautionary measures are to be adhered to when handling chemicals.
- Respiratory protection: Suitable respiratory protective device recommended.
- Protection of hands:
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

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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.

· Body protection: Protective work clothing

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form: Crystalline powder

Colour: White

· Odour: Recognizable

· Odour threshold: Not determined.

· pH-value: Not applicable.

· Change in condition

Melting point/Melting range: 167-174 °C (333-345 °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:

Soluble.

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· 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: Possible in traces.

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.
- Additional ecological information:
- General notes:
 - Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water
 - Do not allow product to reach ground water, water course or sewage system, even in small quantities.
 - Danger to drinking water if even extremely small quantities leak into the ground.
- Results of PBT and vPvB assessment
- PBT: Not applicable.
- vPvB: Not applicable.
- Other adverse effects No further relevant information available.

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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.
- Recommended cleansing agents: Water, if necessary together with cleansing agents.

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 |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · Transport/Additional information: | Not dangerous according to the above specifications. |
| · 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

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· 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

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

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