

## 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](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



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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# Safety data sheet

according to 1907/2006/EC, Article 31

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Version number 6

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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:  
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  
Formation of toxic gases is possible during heating or in case of fire.  
Hydrogen chloride (HCl)  
Carbon monoxide (CO)  
Sulphur dioxide (SO<sub>2</sub>)
- 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 trough 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](mailto: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)

USA