1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier
Chemical Name Milnicpran HCL

Other means of identification
Product Code 101152-94-7
Synonyms Midalcipran, Toledomin Savella

Recommended use of the chemical and restrictions on use
Recommended Use Fibromyalgia

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Details of the supplier of the safety data sheet
Manufacturer ALLERGAN
400 Interpace Parkway, Morris Corporate Center III
Parsippany, NJ 07054, USA
+1-800-272-5525
E-mail address SDS@Allergan.com

Emergency telephone number
Emergency Telephone Call CHEMTREC Day or Night
Within USA or Canada: 1-800-424-9300
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status
This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

<table>
<thead>
<tr>
<th>Acute toxicity - Oral</th>
<th>Category 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive toxicity</td>
<td>Category 2</td>
</tr>
</tbody>
</table>

Label elements

Emergency Overview

Danger

Hazard statements
H301 - Toxic if swallowed
H361 - Suspected of damaging fertility or the unborn child
Precautionary statements

P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
P321 - Specific treatment (see supplemental first aid instructions on this label)
P330 - Rinse mouth
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P405 - Store locked up
P501 - Dispose of contents/container to an approved waste disposal plant
P280 - Wear protective gloves/protective clothing/eye protection/face protection

Other Information

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No.</th>
<th>EINECS</th>
<th>Weight-%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milnicpran HCL</td>
<td>101152-94-7</td>
<td>N/A</td>
<td>100</td>
</tr>
</tbody>
</table>

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

First aid measures

General advice

If symptoms persist, call a physician. Do not breathe dust/fume/gas/mist/vapors/spray. Do not get in eyes, on skin, or on clothing.

Eye contact

Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. If symptoms persist, call a physician.

Skin Contact

Consult a physician if necessary. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
**Inhalation**
Remove to fresh air. Call a physician. If breathing is irregular or stopped, administer artificial respiration. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.

**Ingestion**
Rinse mouth. Drink plenty of water. If symptoms persist, call a physician. Do NOT induce vomiting.

**Chemical Name**
Milnacpran HCL

**Note to physicians**
There is no specific antidote to Savella, but if serotonin syndrome ensues, specific treatment (such as with cyproheptadine and/or temperature control) may be considered. In case of acute overdose, treatment should consist of those general measures employed in the management of overdose with any drug. An adequate airway, oxygenation, and ventilation should be assured and cardiac rhythm and vital signs should be monitored. Induction of emesis is not recommended. Gastric lavage with a large-bore orogastric tube with appropriate airway protection, if needed, may be indicated if performed soon after ingestion or in symptomatic patients. Because there is no specific antidote for Savella, symptomatic care and treatment with gastric lavage and activated charcoal should be considered as soon as possible for patients who experience a Savella overdose.

---

**5. FIRE-FIGHTING MEASURES**

**Suitable extinguishing media**
Dry chemical, CO2 or water spray. Dry chemical, CO2, alcohol-resistant foam or water spray. Move containers from fire area if you can do it without risk. Dike fire control water for later disposal; do not scatter the material.

**Unsuitable extinguishing media**
None known.

**Specific hazards arising from the chemical**
Some are oxidizers and may ignite combustibles (wood, paper, oil, clothing, etc.).

**Explosion data**

- **Sensitivity to Mechanical Impact**: Not impact sensitive.
- **Sensitivity to Static Discharge**: Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

**Protective equipment and precautions for firefighters**
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

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**6. ACCIDENTAL RELEASE MEASURES**

**Personal precautions**
ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Stop leak if you can do it without risk.

**Other Information**
Do not get water inside containers or in contact with substance.

**Environmental precautions**
Prevent entry into waterways, sewers, basements or confined areas. Do not flush into surface water or sanitary sewer system. See Section 12 for additional ecological information.

**Methods for containment**
Absorb or cover with dry earth, sand or other non-combustible material and transfer to containers.

**Methods for cleaning up**
Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate
containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Advice on safe handling
Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Wash contaminated clothing before reuse. Do not breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product.

Storage Conditions
Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children.

Incompatible materials

8. EXPOSURE CONTROLS/PERSOAL PROTECTION

Control parameters

Exposure Guidelines
This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH IDLH</th>
<th>Allergan OEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milnicpran HCL 101152-94-7</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>12.5</td>
</tr>
</tbody>
</table>

Appropriate engineering controls

Engineering Controls
The following requirements list high level controls designed to control exposure below the OEL. More specific requirements may apply.

Powder Handling
LEV or Down flow booth or ventilated enclosure

Solutions/Suspensions and coated tablet handling (no powders or aerosols)
Not Applicable

Packaging (uncoated tablets, hot side work)
Appropriate contained transfer device WIP/CIP for the hopper (if possible), and contained ventilated filler

Laboratory Powder Handling or aerosol generation
VBSE, BSC or Glove Box

Personal Decontamination Procedure/Controls
Required
Unless, In controlled containment: Recommended.

Individual protection measures, such as personal protective equipment

PPE
The following high level PPE requirements assume Engineering Controls that reduce exposure below the limit are not in place. More specific requirements may apply

Powder Handling
PAPR with full hooded top with max APF and HEPA filter or supplied air, gloves

Solutions/Suspensions and coated tablet handling (no powders or aerosols)
Gloves, long sleeved GMP clothing and safety equipment for the area

Packaging (uncoated tablets, hot side work)
1/2 mask, gloves, long sleeved GMP clothing and safety equipment for the area

Laboratory Powder Handling or aerosol generation
Minimum lab PPE gloves No controls-controlled area, min lab PPE, gloves and appropriately fitted 1/2 mask for powders

Eye/face protection
Tight sealing safety goggles.
9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Solid</td>
</tr>
<tr>
<td>Color</td>
<td>White</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No information available</td>
</tr>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Odor</td>
<td>No information available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>No information available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>179 °C / 354 °F</td>
</tr>
<tr>
<td>Boiling point / boiling range</td>
<td>No information available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No information available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No information available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No information available</td>
</tr>
<tr>
<td>Flammability Limit in Air</td>
<td></td>
</tr>
<tr>
<td>Upper flammability limit</td>
<td>No information available</td>
</tr>
<tr>
<td>Lower flammability limit</td>
<td>No information available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No information available</td>
</tr>
<tr>
<td>Vapor density</td>
<td>No information available</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>No information available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>completely soluble</td>
</tr>
<tr>
<td>Solubility in other solvents</td>
<td>No information available</td>
</tr>
<tr>
<td>Partition coefficient</td>
<td>No information available</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No information available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No information available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No information available</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>No information available</td>
</tr>
</tbody>
</table>

Other Information

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular weight</td>
<td>282.81</td>
</tr>
<tr>
<td>VOC Content (%)</td>
<td>No information available</td>
</tr>
<tr>
<td>Density</td>
<td>No information available</td>
</tr>
<tr>
<td>Bulk density</td>
<td>No information available</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Reactivity
Not defined As Reactive substance

Chemical stability
Stable under normal conditions.

Possibility of Hazardous Reactions
None under normal processing.

Conditions to avoid
Aerosol formation.

Incompatible materials

Hazardous Decomposition Products
None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Acute toxicity

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalation LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milnicpran HCL</td>
<td>= 213 mg/kg (Rat)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>
# Delayed and immediate effects as well as chronic effects from short and long-term exposure

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Germ cell mutagenicity</th>
<th>Carcinogenicity</th>
<th>Reproductive toxicity</th>
<th>Effects on or via lactation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milnicpran HCL</td>
<td>Not mutagenic in the standard battery of tests.</td>
<td>Dietary administration of milnacipran to rats at doses of 50 mg/kg/day (2 times the MRHD on a mg/m² basis) for 2 years caused a statistically significant increase in the incidence of thyroid C-cell adenomas and combined adenomas and carcinomas in males. A carcinogenicity study was conducted in Tg.rasH2 mice for 6 months at oral gavage doses of up to 125 mg/kg/day. Milnacipran did not induce tumors in Tg.rasH2 mice at any dose tested.</td>
<td>Milnacipran was shown to increase embryo fetal and perinatal lethality in rats and the incidence of a minor skeletal variation in rabbits at doses below (rat) or approximately equal to (rabbit) the maximum recommended human dose (MRHD) of 200 mg/day on a mg/m² basis. No effects were seen in mice when treated with milnacipran during the period of organogenesis at doses up to 3 times the MHRD on a mg/m² basis.</td>
<td>It is not known whether this drug is excreted in human milk. Because most drugs are excreted in human milk, if use of this drug is deemed essential, the patient should stop nursing.</td>
</tr>
</tbody>
</table>

## Target Organ Effects

Central nervous system.

### Numerical measures of toxicity - Product Information

The following values are calculated based on chapter 3.1 of the GHS document.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATEmix (oral)</td>
<td>213 mg/kg</td>
</tr>
</tbody>
</table>

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

No information available.

### Other adverse effects

No information available.

## 13. DISPOSAL CONSIDERATIONS

### Waste treatment methods

#### Disposal of wastes

Disposal should be in accordance with applicable regional, national and local laws and regulations.

#### Contaminated packaging

Do not reuse container. Dispose of contents/containers in accordance with local regulations.

## 14. TRANSPORT INFORMATION

<table>
<thead>
<tr>
<th>Agency</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOT</td>
<td>Not regulated</td>
</tr>
<tr>
<td>TDG</td>
<td>Not regulated</td>
</tr>
<tr>
<td>ICAO (air)</td>
<td>Not regulated</td>
</tr>
<tr>
<td>IATA</td>
<td>Not regulated</td>
</tr>
</tbody>
</table>
selective norepinephrine and serotonin reuptake inhibitor.

International Inventories

<table>
<thead>
<tr>
<th>TSCA</th>
<th>Not Listed</th>
</tr>
</thead>
<tbody>
<tr>
<td>DSL/NDSL</td>
<td>Not Listed</td>
</tr>
<tr>
<td>EINECS/ELINCS</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

US Federal Regulations

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

<table>
<thead>
<tr>
<th>Hazard Category</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute health hazard</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic Health Hazard</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Fire hazard</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Sudden release of pressure hazard</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Reactive Hazard</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

CWA (Clean Water Act)
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

US State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals

U.S. State Right-to-Know Regulations

16. OTHER INFORMATION

Revision Date 09-Mar-2017
Revision Note No information available
Disclaimer
The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.