



SAFETY DATA SHEET

Revision Date 09-Mar-2017

Version 1.01

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)

Acute toxicity - Oral	Category 3
Reproductive toxicity	Category 2

Label elements

Emergency Overview

Danger

Hazard statements

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

**Appearance** powder**Physical state** Solid**Odor** No information available**Chemical Name**
Milnicpran HCL**Symptoms**

In the placebo-controlled fibromyalgia patient trials, the most frequently occurring adverse reaction in clinical trials was nausea. The most common adverse reactions (incidence \geq 5% and twice placebo) in patients treated with Savella were constipation, hot flush, hyperhidrosis, vomiting, palpitations, heart rate increased, dry mouth, and hypertension.

Chemical Name
Milnicpran HCL**Medical Conditions Aggravated by Exposure**

Renal Impairment patient being treated with linezolid or intravenous methylene blue because there is increased risk of serotonin syndrome. The use of Savella within 14 days of stopping an MAOI intended to treat psychiatric disorders is also contraindicated.

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**

Chemical Name	CAS No.	EINECS	Weight-%
Milnicpran HCL	101152-94-7	N/A	100

*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
Milnicpran 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.

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	Strong oxidizing agents. Nitrogen oxides (NOx). Carbon oxides. Hydrogen chloride.

8. EXPOSURE CONTROLS/PERSONAL 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.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH	Allergan OEL
Milnicpran HCL 101152-94-7	N/A	N/A	N/A	12.5

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

Physical state	Solid	Appearance	powder
Color	White	Odor	No information available
Odor threshold	No information available		

Property

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

Values

Other Information

Molecular weight	282.81
VOC Content (%)	No information available
Density	No information available
Bulk density	No information available

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

Strong oxidizing agents. Nitrogen oxides (NOx). Carbon oxides. Hydrogen chloride.

Hazardous Decomposition Products

None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Acute toxicity

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Milnicpran HCL	= 213 mg/kg (Rat)	N/A	N/A

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
Milnicpran HCL	Not mutagenic in the standard battery of tests.	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.	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.	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.

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 .
 ATEmix (oral) 213 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity

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

DOT Not regulated

TDG Not regulated

ICAO (air) Not regulated

IATA Not regulated

IMDG	Not regulated
ADR	Not regulated
ADN	Not regulated

15. REGULATORY INFORMATION

selective norepinephrine and serotonin reuptake inhibitor.

International Inventories

TSCA	Not Listed
DSL/NDSL	Not Listed
EINECS/ELINCS	Not Listed

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

Acute health hazard	Yes
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

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.

End of Safety Data Sheet