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

Product identifier
Product Name FETZIMA

Other means of identification
Product Code FG00141
Synonyms Levomilnacipran Capsules

Recommended use of the chemical and restrictions on use
Recommended Use Serotonin and norepinephrine reuptake inhibitor (SNRI) indicated for the treatment of Major Depressive Disorder (MDD) in adults.

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 plc
5 Giralda Farms
Madison, NJ USA 07940
+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 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive toxicity</td>
<td>Category 2</td>
</tr>
</tbody>
</table>

Label elements

Emergency Overview

Warning

Hazard statements
H302 - Harmful 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 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
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
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P281 - Use personal protective equipment as required
P330 - Rinse mouth

Other Information

Unknown Acute Toxicity

25% of the mixture consists of ingredient(s) of unknown toxicity

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous

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>Levomilnacipran</td>
<td>96847-55-1</td>
<td>N/A</td>
<td>15 - 40*</td>
</tr>
<tr>
<td>ETHYLCELLULOSE NF ETHOCEL 100</td>
<td>9004-57-3</td>
<td>N/A</td>
<td>10 - 30*</td>
</tr>
<tr>
<td>Povidone USP/PLASDONE K-29-32</td>
<td>9003-39-8</td>
<td>N/A</td>
<td>7 - 13*</td>
</tr>
<tr>
<td>TALC USP (1656)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
<td>3 - 7*</td>
</tr>
<tr>
<td>Confectioners Sugar 6XWith Corn Starch</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>3 - 7*</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
Levomilnacipran

Note to physicians
WARNING: SUICIDAL THOUGHTS AND BEHAVIORS
Increased risk of suicidal thinking and behavior in children, adolescents, and young adults taking antidepressants. Monitor for worsening and emergence of suicidal thoughts and behaviors. This medication is not approved for pediatric patients.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
Fire may produce irritating, corrosive and/or toxic gases.

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.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions
Use personal protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

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
Prevent further leakage or spillage if safe to do so.

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**
None known based on information supplied.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Control parameters

#### Exposure Guidelines

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH IDLH</th>
<th>Allergen OEL (ug/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levomilnacipran 96847-55-1</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>100</td>
</tr>
<tr>
<td>TALC USP(1656) 14807-96-6</td>
<td>TWA: 2 mg/m³ particulate matter containing no asbestos and &lt;1% crystalline silica, respirable particulate matter</td>
<td>(vacated) TWA: 2 mg/m³ respirable dust &lt;1% Crystalline silica, containing no Asbestos; TWA: 20 mppcf if 1% Quartz or more; use Quartz limit IDLH: 1000 mg/m³ containing no Asbestos and &lt;1% Quartz respirable dust</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>CONFECTIONERS SUGAR 6XWITH CORN STARCH 57-50-1</td>
<td>TWA: 10 mg/m³</td>
<td>TWA: 15 mg/m³ total dust (vacated) TWA: 15 mg/m³ total dust (vacated) TWA: 5 mg/m³ respirable fraction</td>
<td>TWA: 10 mg/m³ total dust TWA: 5 mg/m³ respirable dust</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**NIOSH IDLH Immediately Dangerous to Life or Health**

**Other Information**
Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

**Appropriate engineering controls**

**Engineering Controls**
The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

### Individual protection measures, such as personal protective equipment

**Eye/face protection**
No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.

**Skin and body protection**
During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).

**Respiratory protection**
Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Information on basic physical and chemical properties**
**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**
None known based on information supplied.

**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>Levomilnacipran</td>
<td>238 mg/kg (Rat)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>ETHYCELLULOSE NF ETCHOCEL 100</td>
<td>&gt; 5 g/kg (Rat)</td>
<td>&gt; 5 g/kg (Rabbit)</td>
<td>N/A</td>
</tr>
<tr>
<td>PVPIDONE USP (PLASDONE K-29-32)</td>
<td>= 100 g/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>Levomilnacipran</td>
<td>Levomilnacipran was not mutagenic in the in vitro bacterial mutation assay (Ames test) and was not clastogenic in an in vivo micronucleus assay in rats. Additionally, levomilnacipran was not genotoxic in the in vitro mouse lymphoma (L5178Y TK+/-) cell forward mutation assay.</td>
<td>Levomilnacipran administered by oral gavage to rats for 2 years and tg.rasH2 mice for 6 months did not increase the incidence of tumors in either study.</td>
<td>When levomilnacipran was administered orally to male and female rats before mating, through mating and up to day 7 of gestation at doses up to 100mg/kg/day, no effects were observed on fertility. This dose is 8 times the MRHD. Levomilnacipran was not teratogenic in rats or rabbits when given during the period of organogenesis at doses up to 8 or 16 times the maximum recommended human dose (MRHD) of 120 mg on a mg/m2 basis, respectively. However, an increase in early postnatal rat pup mortality was seen at a dose equivalent to 5 times the MRHD given during pregnancy and lactation.</td>
<td>It is not known whether this medication is present in human milk. Studies have shown that this medication is present in the milk of lactating rats. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from this medication, a decision should be made whether to discontinue the drug, taking into account the importance of the drug to the mother.</td>
</tr>
</tbody>
</table>

### Target Organ Effects
Central nervous system, Central Vascular System (CVS), Eyes, Respiratory system.

### Numerical measures of toxicity - Product Information

**Unknown Acute Toxicity**
25% of the mixture consists of ingredient(s) of unknown toxicity

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

<table>
<thead>
<tr>
<th>ATEmix (oral)</th>
<th>493 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATEmix (dermal)</td>
<td>15015 mg/kg</td>
</tr>
<tr>
<td>ATEmix (inhalation-vapor)</td>
<td>11941.3 mg/l</td>
</tr>
</tbody>
</table>

### 12. ECOLOGICAL INFORMATION

**Ecotoxicity**
95% of the mixture consists of component(s) of unknown hazards to the aquatic environment

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Algae/aquatic plants</th>
<th>Fish</th>
<th>Crustacea</th>
</tr>
</thead>
<tbody>
<tr>
<td>TALC USP(1656)</td>
<td>N/A</td>
<td>100: 96 h Brachydano rerio g/L LC50</td>
<td>N/A</td>
</tr>
<tr>
<td>14807-96-6</td>
<td></td>
<td>semi-static</td>
<td></td>
</tr>
</tbody>
</table>

**Other adverse effects**
No information available

### 13. DISPOSAL CONSIDERATIONS

**Waste treatment methods**
Disposal should be in accordance with applicable regional, national and local laws and regulations.

**Disposal of wastes**
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

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

Carcinogenicity
The table below indicates whether each agency has listed any ingredient as a carcinogen.
This product contains one or more substances which are classified by IARC as carcinogenic to humans (Group I), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B).

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>POVIDONE USP(PLASDONE K-29-32)</td>
<td>-</td>
<td>Group 3</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>9003-39-8</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TALC USP(1656)</td>
<td>-</td>
<td>Group 3</td>
<td>-</td>
<td>X</td>
</tr>
<tr>
<td>14807-96-6</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

IARC (International Agency for Research on Cancer)
OSHA (Occupational Safety and Health Administration of the US Department of Labor)
X - Present

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>Pennsylvania</th>
</tr>
</thead>
<tbody>
<tr>
<td>Titanium Dioxide</td>
<td></td>
<td>-</td>
<td>X</td>
</tr>
<tr>
<td>1317-70-0</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>TALC USP(1656)</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>14807-96-6</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONFECTIONERS SUGAR</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>6XWITH CORN STARCH 57-50-1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Revision Date: 02-Oct-2018
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