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

Product identifier
Product Name Citalopram Hydrobromide Tablets

Other means of identification
Product Code FG00107
Synonyms Celexa Tablets

Recommended use of the chemical and restrictions on use
Recommended Use Selective Serotonin Re-uptake Inhibitors Antidepressant

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 not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.122)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label elements

Emergency Overview

The product contains no substances which at their given concentration, are considered to be hazardous to health

Appearance Tablet
Physical state Solid
Odor No information available

Chemical Name Citalopram Hydrobromide
Symptoms Nausea, vomiting, and excitation of the CNS (anxiety, restlessness, nervousness, and insomnia) are considered to be the most frequent effects. Excessive sweating and skin rashes have also been reported. Hypersensitivity effects (angioedema and anaphylactoid reactions) have occurred.
FG00107 Citalopram Hydrobromide Tablets

Other Information
Unknown Acute Toxicity
5% 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>MICROCRYSTALLINE CELLULO (AVICEL PH102)</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>60 - 100*</td>
</tr>
<tr>
<td>MANNITOL USP</td>
<td>69-65-8</td>
<td>200-711-8</td>
<td>10 - 30*</td>
</tr>
<tr>
<td>Citalopram Hydrobromide</td>
<td>59729-33-8</td>
<td>261-891-1</td>
<td>3 - 7*</td>
</tr>
<tr>
<td>Trospium Chloride</td>
<td>10405-02-4</td>
<td>233-875-4</td>
<td>0.1 - 1*</td>
</tr>
<tr>
<td>Povidone USP (Plasdone K-29-32)</td>
<td>9003-39-8</td>
<td>N/A</td>
<td>&lt;0.1*</td>
</tr>
</tbody>
</table>

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

4. FIRST AID MEASURES

First aid measures

Eye contact
Rinse immediately with plenty of water and seek medical advice.

Skin Contact
Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Inhalation
Remove to fresh air.

Ingestion
Consult a physician if necessary.

Chemical Name
Citalopram Hydrobromide

Note to physicians
In clinical trials of citalopram, there were reports of citalopram overdose, including overdoses of up to 2,000 mg, with no associated fatalities. During the post marketing evaluation of citalopram, overdoses of up to 6,000 mg have been reported. As with other SSRI's, a fatal outcome in a patient who has taken an overdose of citalopram has been rarely reported. Symptoms most often accompanying citalopram overdose, alone or in combination with other drugs and/or alcohol, included dizziness, sweating, nausea, vomiting, tremor, somnolence, and sinus tachycardia. In more rare cases, observed symptoms included amnesia, confusion, coma, convulsions, hyperventilation, cyanosis, rhabdomyolysis, and ECG changes (including QTc prolongation, nodal rhythm, ventricular arrhythmia, and one possible case of torsades de pointes).

Trospium Chloride

Trospium chloride is contraindicated in patients with urinary retention, gastric retention, uncontrolled narrow-angle glaucoma, and known hypersensitivity to the drug or its ingredients.
Angioedema, rash and anaphylactic reaction have been reported.

## 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.

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

### Environmental precautions
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. Avoid generation of dust. Do not eat, drink or smoke when using this product.

### Storage Conditions
Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.

### 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>MICROCRYSTALLINE CELLULO(AVICEL PH102) 9004-34-6</td>
<td>TWA: 10 mg/m³</td>
<td>TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction (vacated) TWA: 15 mg/m³ total dust (vacated) TWA: 5 mg/m³ respirable fraction (vacated) TWA: 5 mg/m³ (vacated) STEL: 10 mg/m³</td>
<td>TWA: 10 mg/m³ total dust TWA: 5 mg/m³ respirable dust TWA: 1 mg/m³</td>
<td>N/A</td>
</tr>
<tr>
<td>Citalopram Hydrobromide 59729-33-8</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>13</td>
</tr>
<tr>
<td>Trospium Chloride</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>100 ug/m³³</td>
</tr>
</tbody>
</table>
**FG00107 Citalopram Hydrobromide Tablets**

**Revision Date** 29-Sep-2018

| 10405-02-4 |

**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.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical state</strong></td>
<td>Solid</td>
</tr>
<tr>
<td><strong>Color</strong></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>Odor threshold</strong></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>Appearance</strong></td>
<td>Tablet</td>
</tr>
<tr>
<td><strong>Odor</strong></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>Melting point/freezing point</strong></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>Boiling point / boiling range</strong></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>Flash point</strong></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>Flammability (solid, gas)</strong></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>Flammability Limit in Air</strong></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>Upper flammability limit:</strong></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>Lower flammability limit:</strong></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>Vapor pressure</strong></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>Vapor density</strong></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>Specific Gravity</strong></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>Water solubility</strong></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>Solubility in other solvents</strong></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>Partition coefficient</strong></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>Autoignition temperature</strong></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>Decomposition temperature</strong></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>Explosive properties</strong></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>Oxidizing properties</strong></td>
<td>No information available</td>
</tr>
</tbody>
</table>

**Other Information**
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>Inhalation</th>
<th>Eye contact</th>
<th>Skin Contact</th>
<th>Ingestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Citalopram Hydrobromide</td>
<td>See Symptoms for more information.</td>
<td>See Symptoms for more information.</td>
<td>See Symptoms for more information.</td>
<td>May cause irritation and malaise.</td>
</tr>
<tr>
<td>Trospium Chloride</td>
<td>If airborne dusts generated by this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect continues after removal to fresh air.</td>
<td>Contact with the eyes of airborne dusts generated by this compound may cause mild to moderate irritation, redness, and tearing (mechanical irritation).</td>
<td>In therapeutic use, this compound has caused swelling of the skin, rash and anaphylactic reactions. Angioedema of the face, lips, tongue and/or larynx has been reported with therapeutic use of Trospium. Angioedema associated with upper airway swelling may be life threatening. May cause irritation to skin. Prolonged or repeated skin contact may cause dermatitis (dry, red skin).</td>
<td>If this compound is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Rinse mouth with water immediately. Victim should drink large quantities of water. If milk is available, victim should drink it after drinking water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalation LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>MICROCRYSTALLINE CELLULO(AVICEL PH102)</td>
<td>&gt; 5 g/kg ( Rat )</td>
<td>&gt; 2 g/kg ( Rabbit )</td>
<td>&gt; 5800 mg/m³ ( Rat ) 4 h</td>
</tr>
<tr>
<td>MANNITOL USP</td>
<td>= 13500 mg/kg ( Rat )</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Trospium Chloride</td>
<td>= 1510 mg/kg ( Rat )</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Povidone 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.
Target Organ Effects  
Eyes, Respiratory system, Skin.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity  5% of the mixture consists of ingredient(s) of unknown toxicity  The following values are calculated based on chapter 3.1 of the GHS document .

- ATEmix (oral)  6140 mg/kg
- ATEmix (dermal)  2702 mg/kg
- ATEmix (inhalation-dust/mist)  7.8 mg/l

12. ECOLOGICAL INFORMATION

Ecotoxicity

99.85% of the mixture consists of components(s) of unknown hazards to the aquatic environment  

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Persistence and degradability</th>
<th>Bioaccumulation</th>
<th>Mobility</th>
<th>Partition coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trospium Chloride 10405-02-4</td>
<td>No information available</td>
<td>No information available</td>
<td>No information available</td>
<td>Log P = 0.70</td>
</tr>
</tbody>
</table>

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
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>MICROCRYSTALLINE CELLULO (AVICEL PH102) 9004-34-6</td>
<td>-</td>
<td>Group 1</td>
<td>Known</td>
<td>X</td>
</tr>
<tr>
<td>Povidone USP/PLASDONE K-29-32 9003-39-8</td>
<td>-</td>
<td>Group 3</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

IARC (International Agency for Research on Cancer)
Group 1 - Carcinogenic to Humans

NTP (National Toxicology Program)
Known - Known Carcinogen

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: No
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 contains the following Proposition 65 chemicals

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>Pennsylvania</th>
</tr>
</thead>
<tbody>
<tr>
<td>MICROCRYSTALLINE CELLULO (AVICEL PH102) - 9004-34-6</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>FERRIC OXIDE NF (RED 30) - 1309-37-1</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>CORN STARCH NF - 9005-25-8</td>
<td>-</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>White Cresin Wax - 8002-74-2</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

**U.S. State Right-to-Know Regulations**

16. OTHER INFORMATION

Revision Date 29-Sep-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