1. IDENTIFICATION

Product identifier

Product Name: Paroxetine Tablets

Synonyms: Paroxetine Tablets; Paroxetine Film-Coated Tablets; Paroxetine Tablets, USP 10 mg; Paroxetine Tablets, USP 20 mg; Paroxetine Tablets, USP 30 mg; Paroxetine Tablets, USP 40 mg

Other means of identification

Other Information: No other information

Recommended use of the chemical and restrictions on use

Recommended Use: Pharmaceutical. Use only as directed.

The intent of this safety data sheet (SDS) is to provide safety information for occupational handling of this product. This information may not be relevant for medical use of this product. Patients/consumers should consult the package insert/product label/physician/pharmacist for information regarding the usage of this product. For information on the ingredients used in this product, refer to the appropriate SDS for each ingredient.

Uses advised against: No information available.

Details of the supplier of the safety data sheet

Mylan Inc.
Robert J. Coury Global Center
1000 Mylan Blvd.
Canonsburg, PA 15317, USA
+1.724.514.1800

Contact e-mail: SDScontact@mylan.com

Emergency telephone number

Emergency Telephone:
For Hazardous Materials Incident
Spill, Leak, Fire, Exposure, or Accident
Call CHEMTREC (24 Hours)
Worldwide: +1 703-741-5970

Other Contact Information

FDA Adverse Events Reporting
Number: For reporting adverse health events call:
+1 877-446-3679

2. HAZARDS IDENTIFICATION

Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician’s directions.

This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and by Canada’s Food and Drugs Act. It is in solid, final form for direct administration to the patient. Therefore, it is exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(6)(vii) and in Canada’s Hazardous Products Act

Classification

Not classified

Label elements

Not classified

Other Hazards

No information available.

Unknown acute toxicity

No information available
3. COMPOSITION/INFORMATION ON INGREDIENTS

This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and by Canada’s Food and Drugs Act. It is in solid, final form for direct administration to the patient. Therefore, it is exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(6)(vii) and in Canada’s Hazardous Products Act.

4. FIRST AID MEASURES

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

**Description of first aid measures**

**Overdose:** Refer to information on package labeling and packaging. In case of overdose, get medical help or contact a Poison Control Center right away.

**General advice:** Show this safety data sheet to the doctor in attendance.

**Inhalation:** IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention immediately if symptoms occur.

**Skin contact:** Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention.

**Eye contact:** In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

**Ingestion:** Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.

**Self-protection of the first aider:**

- **First aider:** Pay attention to self-protection. Do not breathe dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

**Most important symptoms and effects, both acute and delayed**

**Symptoms:** May cause central nervous system depression with nausea, headache, dizziness, vomiting, and incoordination.

**Chronic symptoms:** May cause adverse reproductive effects - such as birth defect, miscarriages, or infertility.

**Indication of any immediate medical attention and special treatment needed**

Treat symptomatically. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

5. FIRE-FIGHTING MEASURES

**Extinguishing media**

**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 hazard:** Not flammable.
- **Explosive hazard:** Not an explosive.
- **Reactivity:** Hazardous reactions will not occur under normal conditions.

**Advice for firefighters**

- **Precautionary measures in case of fire:** Standard procedure for chemical fires.
- **Firefighting instructions:** Use water spray or fog; do not use straight streams.
- **Protection of Firefighters:** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

**Other Information:** Refer to Section 9 for flammability properties.

6. ACCIDENTAL RELEASE MEASURES

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

**Personal precautions, protective equipment and emergency procedures**

**Personal precautions:** Avoid contact with skin, eyes or clothing. Do not breathe dust/fume/gas/mist/vapors/spray. Use personal protective equipment as required.

**For non-emergency personnel**

- **Personal Protective Equipment:** Use personal protective equipment as required.
- **Emergency procedures:** Evacuate personnel to safe areas.

**For emergency responders**

- **Personal Protective Equipment:** Use personal protective equipment as required.
- **Emergency procedures:** Evacuate personnel to safe areas. Ventilate the area. Eliminate all ignition sources if safe to do so.

**Environmental precautions**

Do not flush into surface water or sanitary sewer system. Should not be released into the environment. See Section 12 for additional Ecological Information.

**Methods and material for containment and cleaning up**

**Methods for containment:** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up:** Use appropriate personal protective equipment (PPE). Carefully shovel or sweep up spilled material and place in
suitable container. Avoid generating dust. For spills: Soak up with inert absorbent material. Use clean non-sparking tools to collect absorbed material. Avoid breathing dust or spray mist.

Prevention of secondary hazards: Clean contaminated objects and areas thoroughly observing environmental regulations.

Reference to other sections
See section 8 for more information. See section 13 for more information.

7. HANDLING AND STORAGE
Precautions for safe handling
Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician’s directions.
Advice on safe handling: Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes.
Conditions for safe storage, including any incompatibilities.
Specific end use(s): Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION
This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.
Control parameters
Exposure Limits: No information available
Exposure controls
Appropriate engineering controls: Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.
Individual protection measures, such as personal protective equipment
Hand protection: Wear suitable gloves.
Eye/face protection: Safety glasses with side shields are recommended for medical or industrial exposures.
Skin and body protection: Wear suitable protective clothing.
Respiratory protection: Use appropriate respiratory protection.
General hygiene considerations: Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES
Information on basic physical and chemical properties
Physical state: Solid
Appearance: tablet
Color: blue
Odor: No data available
Odor threshold: No data available
pH: No data available
Melting point / freezing point: No data available
Boiling point / boiling range: No data available
Flash point: No data available
Evaporation rate: No data available
Flammability (solid, gas): No data available
Upper flammability limit: No data available
Lower flammability limit: No data available
Vapor pressure: No data available
Vapor density: No data available
Relative density: No data available
Water solubility: No data available
Solubility in other solvents: No data available
Partition coefficient: No data available
Autoignition temperature: No data available
Decomposition temperature: No data available
Kinematic viscosity: No data available
Dynamic viscosity: No data available
Explosive properties: No data available
Oxidizing properties: No data available
Paroxetine Tablets

Other Information
VOC Content (%):  No data available

10. STABILITY AND REACTIVITY

Reactivity
Hazardous reactions will not occur under normal conditions.

Chemical stability
Stable under normal conditions.

Possibility of hazardous reactions
None under normal processing.

Conditions to avoid
Extremes of temperature and direct sunlight.

Incompatible materials
Strong oxidizing agents, strong acids, and strong bases.

Hazardous decomposition products
Decomposition will not occur under normal conditions.

11. TOXICOLOGICAL INFORMATION

Information on toxicological effects
Information on likely routes of exposure
Inhalation: Not an expected route of exposure.
Ingestion: May be harmful if swallowed in amounts above the therapeutic dose.
Eye contact: Not an expected route of exposure.
Skin contact: Not an expected route of exposure.

Symptoms related to the physical, chemical and toxicological characteristics
Symptoms: May cause central nervous system depression with nausea, headache, dizziness, vomiting, and incoordination.

Delayed and immediate effects as well as chronic effects from short and long-term exposure
Skin corrosion/irritation: Not applicable.
Serious eye damage/eye irritation: Not applicable.
Respiratory or skin sensitization: Not applicable.
Germ cell mutagenicity: Based on available data, the classification criteria are not met.
Carcinogenicity: Based on available data, the classification criteria are not met.
Reproductive toxicity: Contains a known or suspected reproductive toxin.
STOT - single exposure: Based on available data, the classification criteria are not met.
STOT - repeated exposure: Based on available data, the classification criteria are not met.
Aspiration hazard: Based on available data, the classification criteria are not met.

Numerical measures of toxicity
Acute toxicity: No information available

12. ECOLOGICAL INFORMATION

Ecotoxicity
Harmful to aquatic life with long lasting effects.

Persistence and degradability
No information available.

Bioaccumulation
No information available.

Mobility
No information available.

Other adverse effects
No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods
Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable. Dispose of waste in accordance with environmental legislation. Do not flush into surface water or sanitary sewer system.

14. TRANSPORT INFORMATION

Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.

In accordance with DOT / ICAO / IATA / TDG.
Paroxetine Tablets

UN Number
Not regulated

UN proper shipping name
Not regulated

Transport hazard class(es)
Hazard Class: Not regulated

Packing group
Not regulated

Environmental hazards
No

Special precautions for user
No information available

Transport in bulk according to Annex II of MARPOL and the IBC Code
Not applicable

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

International Regulations
Ozone-depleting substances (ODS): Not applicable
Persistent Organic Pollutants: Not applicable
The Rotterdam Convention: Not applicable

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.

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.

U.S. State Right-to-Know Regulations

US State Regulations:

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>Pennsylvania</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose Microcrystalline (CAS #: 9004-34-6)</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

Canada
This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the CPR.

16. OTHER INFORMATION

Revision Date: 06-September-2019

Other Information: This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warning included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

Key or legend to abbreviations and acronyms used in the safety data sheet:

Legend, Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION
TWA: TWA (time-weighted average)
STEL: STEL (Short Term Exposure Limit)

Party responsible for the preparation of this document:
Mylan Global Environmental, Health, and Safety Department - Occupational Toxicology
Phone number: +1 304-559-2595

06-September-2019  NGHS ( English )  5/6
This SDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Mylan GEHS NA GHS SDS 2017