



SAFETY DATA SHEET

Methylphenidate HCl Extended Release Tablets, USP

1. IDENTIFICATION

Manufacturer:

Ascent Pharmaceuticals Inc
400 S. Technology Drive
Central Islip, NY 11722
USP

Emergency Phone:

1-855-221-1622

Common Name: Methylphenidate HCl Extended Release Tablets, USP

Synonym(s): Not Applicable

Chemical Name: 2-Piperidineacetic acid, α -phenyl-, methyl ester, hydrochloride

Trade Name(s): Methylphenidate HCl Extended Release Tablets, USP 18 mg, 27 mg, 36 mg and 54 mg.

Molecular formula and weight: C₁₄H₁₉NO₂ · HCl

2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Caution Statement Narcotic. Accidental Ingestion of large amounts may be harmful. Read package insert prior to use.

Potential Health Effects

Routes of Entry: Ingestion

Eyes: May cause irritation.

Skin Contact: with skin may cause irritation. Allergic reactions are possible, Rash.

Inhalation: Narcotic. Can irritate the respiratory passages and cause sneezing, coughing, hypersensitivity. Other symptoms will parallel ingestion.

Ingestion: Narcotic. Toxic if swallowed. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Ingestion of this product may result in central nervous system stimulation including muscle twitching, generalized weakness, difficulty breathing and coma. May cause headaches and dizziness, Anxiety, Tachycardia, (excessively rapid heartbeat, including rapid and weak pulse). Hypertension (high blood



pressure), Mental impairment, Confusion, agitation and/or excitation, Tremors, convulsions, Fever, Dryness of mouth and throat.

Effects of Overexposure: Symptoms of overdose include agitation, confusion, convulsions possibly followed by coma.

Chronic exposure: Hypersensitivity, may cause habituation or addiction.

Carcinogenicity: - Not listed by IARC, NTP and OSHA.

3.COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS</u>	<u>Concentration*</u>
		<u>18 mg, 27 mg, 36 mg and 54 mg</u>
METHYLPHENIDATE HYDROCHLORIDE	298-59-9	≈ 7 % to 10 %
Excipients	NA	≈ 90-93 %

* All Concentrations are percent by weight.

4. FIRST AID MEASURES

Inhalation: If breathing is difficult, move to fresh air, if not breathing give artificial respiration. Get medical attention immediately.

Skin Contact: Wash with soap and water for at least 15 minutes. Get medical attention if symptoms occur.

Eye Contact: Any material that contacts the eye should be washed out immediately with water for at least 15 minutes. If easy to do, remove contact lenses if worn. Get medical attention if symptoms persist.

Ingestion: Call a physician or poison control center immediately. Never give anything by mouth to a victim who is unconscious or is having convulsions. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.



5. FIRE-FIGHTING MEASURES

Extinguishing Media: Use water spray, dry chemical, carbon dioxide or material appropriate for fire in surrounding area

Unusual Fire & Explosion Hazards: Not Applicable.

Special Fire Fighting Procedures: Wear full protective clothing and self-contained breathing apparatus.

Protective Measures: Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all firefighting procedures.

Environmental precautions: Do not release in to the environment.

Spill Cleanup methods: Sweep up or vacuum up spillage and collect in suitable container for disposal. Should not be released into the environment. Do not flush to sewer. All clean-up operations should be witnessed by more than one individual. The amount of material collected should be assessed and documented. See section 13 of the SDS.

7. HANDLING AND STORAGE

Handling: Special handling and storage requirements must be observed to assure compliance with Drug Enforcement Administration regulations. All employees who handle this material should be thoroughly trained to handle it safely. Empty containers may contain residual material; therefore, empty containers should be handled with care and disposed of properly. Do not breathe dust. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.

Storage: This material must be stored in a locked cabinet in a Controlled Substance Storage Room, per the requirements of regulations of the DEA and FDA at Controlled Room Temperature: 20° to 25° C (68° to 77° F). Store the medicine in a tight, light resistant container at room temperature, away from heat, moisture, and direct light.



8.EXPOSURE CONTROLS / PERSONAL PROTECTION

Compressed tablets are not considered hazardous under normal handling procedures and protective equipment is not required. The following are recommended for manufacturing or other situations where exposure to the powder may occur.

Protective Measures: Not required when handling tablets or containers. Ventilation should be matched to conditions.

Respiratory Protection: Not required when handling tablets or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.

Hand Protection: Chemical resistant gloves.

Eye Protection: Wear safety glasses with side shields (or goggles). If the work environment or activity involves dusty conditions, mist or aerosols, wear the appropriate goggles. Wear a face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and Body Protection: Not required when handling tablets. If containers are compromised or exposure is likely --wear: Goggles, Lab Coat and Gloves

Hygiene Measures: Wash skin thoroughly with soap and water.

9.PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

Physical State: Solid

Form: Tablets

Appearance:

Methylphenidate HCl Extended Release Tablets, USP 18 mg: Light yellow to yellow film coated, round cylindrical biconvex tablets printed with "212" in black ink.

Methylphenidate HCl Extended Release Tablets, USP 27 mg: Light pink to pink film coated, round cylindrical biconvex tablets printed with "213" in black ink.

Methylphenidate HCl Extended Release Tablets, USP 36 mg: White to Off white film coated, round cylindrical biconvex tablets printed with "214" in black ink.

Methylphenidate HCl Extended Release Tablets, USP 54 mg: Light to dark brown film coated, round cylindrical biconvex tablets printed with "215" in black ink



10. STABILITY AND REACTIVITY

Possibility of hazardous reactions: Stable under ordinary conditions of use and storage.

Conditions to avoid: Excessive heat & Moisture.

Incompatible materials: Alkalis.

Hazardous Decomposition products: May produce Carbon oxides, Nitrogen oxides (NO_x) & Hydrogen chloride.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity:

Active Ingredient:

LD50 Oral (rat): 350 mg/kg

LD50 Oral (mouse): 60 mg/kg

Carcinogenicity: Not listed as a carcinogen or potential carcinogen by NTP, IARC Monographs or OSHA.

12. ECOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.

Ecotoxicity: No data available.

Acute toxicity (Aquatic invertebrates): No data available.

Bioaccumulation: No data available.

Mobility: No data available.

13. DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of waste must be in accordance with all applicable Federal, State and local laws. Notify site Drug Enforcement Agency compliance officer and local DEA office for appropriate disposal procedures. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations.



14. TRANSPORT INFORMATION

DOT: Not Regulated

IMDG: Not regulated

ICAO/IATA: Not Regulated

15. REGULATORY INFORMATION

Stated regulatory information chosen primarily for possible usage of Ascent Pharmaceutical, Inc. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulatory Information

CERLA Hazardous Substance List (40 CFR 302.4): None

TSCA : None

SARA Title III

Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): None

Section 313 Toxic Release Inventory (40 CFR 372): None

Hazard categories Immediate Hazard - Yes

Delayed Hazard - Yes

Fire Hazard - No

Pressure Hazard - No

Reactivity Hazard - No

Drug Enforcement Administration (DEA) List 2, Essential Chemicals (21 CFR 1310.02(b) and 1310.04(f)(2) and Chemical Code Number- Not listed.

Drug Enforcement Administration (DEA). List 1 & 2 Exempt Chemical Mixtures (21 CFR 1310.12(c))-Not regulated.

DEA Exempt Chemical Mixtures Code Number-Not regulated.

16. OTHER INFORMATION

NFPA ratings Health: 3 Flammability: 0 Reactivity: 0

SDS Sections Revised: New



GLOSSARY:

SDS	Safety Data Sheet
NA	Not Applicable
CAS Number	Chemical Abstract Service Registry Number
NTP	National Toxicology Program
NIOSH	National Institute for Occupational Safety and Health
DOT	Department of Transportation
IMDG	International Maritime Dangerous Goods Code
ICAO	International Civil Aviation Organization
IATA	International Air Transport Association
IMO	International Maritime Organization
TSCA	Toxic Substances Control Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
SARA	Superfund Amendments and Reauthorization Act
OSHA	Occupational Safety and Health Administration
DEA	Drug Enforcement Administration

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