



## SAFETY DATA SHEET

**Dexmethylphenidate HCL Extended Release Capsules, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 35 mg and 40mg**

### 1. IDENTIFICATION

**Manufacturer:**

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

**Emergency Phone:**

1-855-221-1622

**Common Name:** Dexmethylphenidate HCL Extended Release Capsules

**Synonym(s):** Not Applicable

### 2. HAZARDS IDENTIFICATION

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

### EMERGENCY OVERVIEW

Non-therapeutic ingestion may be harmful or fatal. Read package insert prior to use

**Classification:** Not classified

**Routes of Entry:** Ingestion, Skin contact

**Label elements:** Not classified

**Other Hazards:** No information available

### 3.COMPOSITION / INFORMATION ON INGREDIENTS

<u><b>Ingredient</b></u>	<u><b>CAS</b></u>	<u><b>Concentration*</b></u>
Dexmethylphenidate Hydrochloride	19262-68-1	6%
Excipients	NA	≈ 94%

\* 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 Capsules 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 Capsules or containers. Ventilation should be matched to conditions.



**Respiratory Protection:** Not required when handling Capsules 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 Capsules. 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:** Capsules

## 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<sub>x</sub>) & Hydrogen chloride.

## 11. TOXICOLOGICAL INFORMATION

**Skin Corrosion/Irritation:** No hazard expected under normal handling conditions.

**Serious eye damage/irritation:** No hazard expected under normal handling conditions.

**Respiratory or skin sensitization:** No hazard expected under normal handling conditions.

**Germ Cell Mutagenicity:** No hazard expected under normal handling conditions.

**Carcinogenicity:** No hazard expected under normal handling conditions.

**Reproductive toxicity:** No hazard expected under normal handling conditions.

**STOT - single exposure:** No hazard expected under normal handling conditions.



**STOT - repeated exposures:** No hazard expected under normal handling conditions.  
**Aspiration hazard** No hazard expected under normal handling conditions.

**Other Information**

No hazard expected under normal handling conditions.

## 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

**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**

This product is a FDA regulated pharmaceutical product that is not classified, not regulated or exempt from requirements contained in 2012 OSHA Hazard Communication Standard (29 CFR 1910.122). The active ingredient, dexamethamphetamine hydrochloride, is a FDA Category 2 Controlled Substance. Consult product packaging insert for additional health and safety information on dosage and potential side effects from use of this product

## **16. OTHER INFORMATION**

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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