



Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Methylphenidate Hydrochloride USP CII

20-3076

Section 1: Identification

Product Name Methylphenidate Hydrochloride USP CII

Commercial Name Not available.

Product Use Active pharmaceutical ingredient

Restrictions On Use Not available.

Product Code 20-3076

Company PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
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In case of emergency contact:
CHEMTREC (24hr) 1-800-424-9300

Section 2: Hazard(s) Identification

OSHA Haz Com: Acute toxicity, oral Category 4 Sensitization, skin Category 1B Specific target organ toxicity, single exposure

CFR 1910.1200 Category 3 narcotic effects

Signal Word WARNING

Hazard Statement(s) Harmful if swallowed. May cause an allergic skin reaction. May cause drowsiness or dizziness. may form combustible dust concentrations in air.

Pictogram(s) or Symbol(s)



Precautionary Statement(s):

Prevention	Prevent dust accumulation to minimize explosion hazard. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Avoid breathing dust. Use only outdoors or in a well-ventilated area. Do not eat, drink or smoke when using this product. Wear protective gloves. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace.
Response	In case of fire: Use appropriate media to extinguish. If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell
Storage	Store in a well-ventilated place. Keep container tightly closed. Store locked up
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.

Section 3: Composition/Information on Ingredients

Substance/Mixture	Substance
Components	Methylphenidate Hydrochloride
% By Weight	100
CAS#	298-59-9
Molecular Weight	269.77 g/mole
Chemical Formula	C14-H19-N-O2.HCl
Synonym(s)	Ritalin, Ritalin hydrochloride, Meridil hydrochloride, Centedrin

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Methylphenidate Hydrochloride	298-59-9	100		(Oral) LD50- 367 mg/kg (Rat) 60mg/kg (Mouse) Investigated as a tumorigen.

Section 4: First-Aid Measures

Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Give oxygen or artificial respiration if needed. Get medical attention immediately!
Skin Contact	Remove and isolate contaminated clothing and shoes. Wash off with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Wash clothing separately before reuse
Eye Contact	Do not rub eyes. Rinse with water. Remove contact lenses, if present and easy to do. Get medical attention if irritation develops and persists
Ingestion	Rinse mouth. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Never give anything by mouth to a victim who is unconscious or is having convulsions. Get medical attention immediately.
Symptoms/Effects	
Acute	Acute exposure may cause vomiting and muscle twitching. Chronic exposure may cause cardiac activity sensitizing effects, drowsiness, dizziness, abdominal pain, anorexia, cough, irritability, insomnia, fever, pharyngitis, mood swings, nausea, headache, diarrhea, fatigue, rash, aggression, anxiety, loss in appetite, throat pain, and weight decrease. Dusts may irritate the respiratory tract, skin and eyes. May cause an allergic skin reaction. Dermatitis. Rash.
Delayed	Acute exposure may cause vomiting and muscle twitching. Chronic exposure may cause cardiac activity sensitizing effects, drowsiness, dizziness, abdominal pain, anorexia, cough, irritability, insomnia, fever, pharyngitis, mood swings, nausea, headache, diarrhea, fatigue, rash, aggression, anxiety, loss in appetite, throat pain, and weight decrease. Dusts may irritate the respiratory tract, skin and eyes. May cause an allergic skin reaction. Dermatitis. Rash.

Immediate Medical Attention

Provide general supportive measures and treat symptomatically. Keep victim warm. Keep victim under observation. Symptoms may be delayed. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before reuse.

Section 5: Fire-Fighting Measures**Suitable Extinguishing Media**

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂). Apply extinguishing media carefully to avoid creating airborne dust. Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture

Unsuitable Extinguishing Media

Do not use water jet as an extinguisher, as this will spread the fire.

Products of Combustion

Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard. During fire, gases hazardous to health may be formed such as: Carbon oxides (CO_x). Nitrogen Oxides (NO_x).

Firefighters Special Equipment and Precautions

In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk. Use standard firefighting procedures and consider the hazards of other involved materials.

Section 6: Accidental Release Measures

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Use only non-sparking tools. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Take precautionary measures against static discharge. Use only non-sparking tools. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Minimize dust generation and accumulation. Collect dust using a vacuum cleaner equipped with HEPA filter. Stop the flow of material, if this is without risk. Large Spills: Wet down with water and dike for later disposal. Absorb in vermiculite, dry sand or earth and place into containers. Shovel the material into waste container. Following product recovery, flush area with water. Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid discharge into drains, water courses or onto the ground

Section 7: Handling and Storage

Minimize dust generation and accumulation. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Explosion-proof general and local exhaust ventilation. Do not taste or swallow. Avoid breathing dust. Avoid contact with eyes, skin, and clothing. When using, do not eat, drink or smoke. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices. Store locked up. Store between 15°C (59°F) and 25°C (77°F). Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS). CONTROLLED SUBSTANCE: Location of storage area must comply with all Drug Enforcement Administration or competent authority regulations.

Section 8: Exposure Controls/Personal Protection**Exposure Limits**

Not available.

Engineering Controls

Explosion-proof general and local exhaust ventilation. Good general ventilation (typically 10 air changes per hour) 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 to an acceptable level. Ventilation should be sufficient to effectively remove and prevent buildup of any dusts or fumes that may be generated during handling or thermal processing. If engineering measures are not sufficient to maintain concentrations of dust particulates below the OEL, suitable respiratory protection must be worn. If material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the recommended exposure limits. Ensure adequate ventilation, especially in confined areas.

Personal Protection

Eye: Chemical goggles are recommended. Provide eyewash station and safety shower. Hand: Wear protective gloves. Other: Wear appropriate gloves; lab coat, nylon coveralls or disposable Tyvek suit; safety glasses, safety shoes, and disposable booties. Respiratory: Where open handling of powders occurs, use a powered, air-purifying respirator (PAPR) with HEPA cartridges or a supplied-air respirator (SAR), unless air-monitoring data has shown that a lower level of respiratory protection is adequate. Thermal: Wear appropriate thermal protective clothing, when necessary. Hygiene: When using, do not eat, drink or smoke. Avoid breathing dust. Avoid contact with eyes. Avoid contact with skin. Avoid contact with clothing. Wash hands after handling and before eating. Handle in accordance with good industrial hygiene and safety practice. See Section 7 for additional information on occupational control measures appropriate for OEB-2 potent compounds.

Section 9: Physical and Chemical Properties

Appearance	White solid. Powder.		
Odor	N/A		
Odor Threshold	Not available.		
Melting Point	417.2°F (214°C) ca.	pH	Not available.
Freezing Point	Not available.	Vapor Pressure	Not available.
Boiling Point/Range	Not available.	Vapor Density	Not available.
Decomposition temperature	458.6°F (237°C) Minimum T	Viscosity	Not available.
Partition Coefficient: n-octanol/water	Not available.	Evaporation Rate	Not available.
Flash Point	Not available.	Autoignition temperature	824°F (440°C) Method: M.I.T. Dust
Flammability	Not available.	Flammability or Explosive Limits:	
		Lower	Not available.
		Upper	Not available.
Solubility(ies)	soluble in water		
Other	Not available.		

Section 10: Stability and Reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability	Material is stable under normal conditions
Hazardous Polymerization	Hazardous polymerization will not occur.
Conditions to Avoid	Keep away from heat, sparks and open flame. Avoid temperatures exceeding the decomposition
Incompatible Materials	Alkalies
Hazardous Decomposition Products	Carbon monoxide. Carbon dioxide. Nitrogen oxides (NOx). Hydrogen chloride

Section 11: Toxicological Information

RTECS	TM3850000
Acute Toxicity	Toxic by inhalation. Toxic if swallowed. Toxic in contact with skin. Oral LD50 Mouse 60 mg/kg Rat 350 mg/kg
Skin Corrosion/Irritation	Dust or powder may irritate the skin. May cause an allergic skin reaction.
Serious Eye Damage/Irritation	Dust may irritate the eyes.
Respiratory or Skin Sensitization	May cause drowsiness and dizziness. Headache. Nausea, vomiting. Dust may irritate respiratory system
Germ Cell Mutagenicity	Not available.
Carcinogenicity	Not available.
Reproductive Toxicity	Not available.
Routes of Entry	

Ingestion: Toxic if swallowed. May be fatal if swallowed. Narcotic effect. Exposure may cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, constipation, respiratory depression; also tolerance, dependence and withdrawal. Confusion, agitation and/or excitation. Tachycardia, (excessively rapid heart beat, including rapid and weak pulse). Hypertension (high blood pressure). Fever. Tremors, convulsions. Unconsciousness. Dryness of mouth and throat. Rash. May cause headaches and dizziness. Large doses can lead to respiratory or cardiac arrest and death Inhalation: Toxic by inhalation. Narcotic effect. Dust irritates the respiratory system, and may cause coughing and difficulties in breathing. Nausea, vomiting. Headache. Sore throat. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause sensitization by inhalation. Symptoms may parallel ingestion. Skin: Toxic in contact with skin. May cause skin irritation. May cause an allergic skin reaction. May cause sensitization by skin contact. Eye: Dust or powder may irritate eye tissue. May irritate and cause redness and pain.

Symptoms Related to Exposure

Narcotic. Exposure may cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, constipation, respiratory depression; also tolerance, dependence and withdrawal. May cause allergic respiratory and skin reactions.

Potential Health Effects

Symptoms may be delayed.

Target Organ(s) Causes damage to organs (Heart). Narcotic effects.

Section 12: Ecological Information**Ecotoxicity**

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and Degradability

Not available.

Bioaccumulative Potential

Not available.

Mobility in Soil

Not available.

Other Adverse Effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Section 13: Disposal Considerations**Waste Disposal**

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. Follow handling guidance appropriate for OEB-2 potent compounds, (see Section 7). Dispose of contents/container (in accordance with related regulations).

Disposal of Container

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see disposal instructions).

Other Considerations

Not available.

Section 14: Transport Information**DOT Classification**

Not a DOT controlled material (United States). This material is not classified dangerous good according to international transportation regulations (ADR/RID-IMDG-ICAO/IATA).

Section 15: Regulatory Information**Regulations**

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. TSCA exempt status. TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D) Not regulated. CERCLA Hazardous Substance List (40 CFR 302.4) Not listed. SARA 304 Emergency release notification Not regulated. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050) Not listed. CERCLA (Superfund) reportable quantity None Superfund Amendments and Reauthorization Act of 1986 (SARA) Hazard categories Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - Yes Pressure Hazard - No Reactivity Hazard - No SARA 302 Extremely hazardous substance Not listed. SARA 311/312 Hazardous chemical Yes Other federal regulations Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List Not regulated. Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130) Not regulated. Safe Drinking Water Act (SDWA) Not regulated. Drug Enforcement Administration (DEA) (21 CFR 1308.11-15) Schedule II - 1724 US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. US. Massachusetts RTK - Substance List Not regulated. US. New Jersey Worker and Community Right-to-Know Act Not listed. US. Pennsylvania Worker and Community Right-to-Know Law Not listed. US. Rhode Island RTK Not regulated. US. California Proposition 65 Not Listed. International Inventories Country(s) or region Inventory name On inventory (yes/no)* Australia Australian Inventory of Chemical Substances (AICS) Yes Canada Domestic Substances List (DSL) Yes Canada Non-Domestic Substances List (NDSL) No China Inventory of Existing Chemical Substances in China (IECSC) No Europe European Inventory of Existing Commercial Chemical Substances (EINECS) Europe European List of Notified Chemical Substances (ELINCS) No Japan Inventory of Existing and New Chemical Substances (ENCS) Yes Korea Existing Chemicals List (ECL) No New Zealand New Zealand Inventory Yes Philippines Philippine Inventory of Chemicals and Chemical Substances No (PICCS) United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory No *A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

Other

Not available.

Section 16: Other Information

PCCA provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. PCCA MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, MALLINCKRODT WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION. Product and Company Identification: Product and Company Identification Exposure controls/personal protection: Thermal hazards Stability and reactivity: Reactivity Toxicological Information: Toxicological Data Toxicological information: Symptoms related to the physical, chemical and toxicological characteristics Other information, including date of preparation or last revision: Further information GHS: Qualifiers