



MATERIAL SAFETY DATA SHEET

PART I *What is the material and what do I need to know in an emergency?*

1. PRODUCT IDENTIFICATION

PRODUCT NAME (AS LABELED): METOCLOPRAMIDE HYDROCHLORIDE INJECTION

SUPPLIER/MANUFACTURER'S NAME: Sicor Pharmaceuticals, Inc.
ADDRESS: 19 Hughes
Irvine, CA 92618

CHEMTREC EMERGENCY NO.: 1-800-424-9300 (United States)**
1-202-483-7616 (International Collect)

BUSINESS PHONE: 1-800-729-9991

FAX: 1-949-855-8210

Common Names: Metoclopramide Hydrochloride
Chemical Name: 2-methoxy-4-amino-5-chloro-N-(2-diethylaminoethyl) benzamide hydrochloride monohydrate.
Chemical Formula: C₁₄H₂₂ClN₃O₂·HCl·H₂O
Chemical Family: Antiemetic agent.
How Supplied: 5 mg/mL in 2 mL vial.

2. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	% by weight	EXPOSURE LIMITS IN AIR					
			ACGIH		OSHA			OTHER
			TLV ppm	STEL ppm	PEL ppm	STEL ppm	IDLH ppm	
METOCLOPRAMIDE HYDROCHLORIDE	54143-57-6	< 1	NE	NE	NE	NE	NE	NE
SODIUM CHLORIDE	7647-14-5	< 1	NE	NE	NE	NE	NE	NE
WATER (for injection)	7732-18-5	>98	NE	NE	NE	NE	NE	NE

* NE = Not Established. **Chemtrec number: Use only in the event of a chemical emergency involving a spill, leak, fire, exposure or accident involving this chemical.

3. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: This clear, colorless solution is toxic by injection and ingestion. It emits hydrogen chloride and nitrogen oxides upon thermal decomposition. It poses no other unusual emergency properties.

SYMPTOMS OF OVER EXPOSURE BY ROUTE OF EXPOSURE: This material may be harmful if ingested or injected into skin. The solution may be irritating to the eyes, skin, mucous membranes and other tissues which are contaminated. Inhalation exposure may also cause symptoms similar to injection.

INHALATION: There is no evidence of inhalation toxicity. This must be considered as lack of sufficient testing rather than the absence of toxicity. Breathing mists or sprays of this material may irritate the respiratory tract.

CONTACT WITH SKIN or EYES: There is no evidence of contact toxicity with the eyes or skin. This must be considered as lack of sufficient testing rather than the absence of toxicity. Broken skin may allow sufficient material to absorb into bloodstream so than an exposed individual can exhibit toxic effects similar to injection. Contact with the solution may be irritating to the skin or eyes.

SKIN ABSORPTION: There is currently no evidence that skin absorption is a significant route of entry for this product.




INGESTION: There is evidence of ingestion toxicity, especially from animal studies. Exposure via ingestion may produce symptoms similar to those of injection exposures, as described below.

INJECTION: Adverse reactions have been observed after injection of this product include the following: extrapyramidal reactions (i.e. involuntary movement of limbs, facial grimaces, speech difficulties); endocrine disturbances (i.e. excessive flow of breast milk, loss of menstrual cycle, breast enlargement); cardiovascular disorders (i.e. hypotension, hypertension); gastrointestinal disorders (i.e. nausea and bowel disturbances, diarrhea); liver problems (i.e. jaundice, altered liver function test); kidney problems (change in urinary frequency and incontinence); and, allergic reactions (rashes, bronchospasms). Other symptoms of exposure can include visual disturbances and depression. Injection exposures have lead to a potentially fatal syndrome (Neuroleptic Malignant Syndrome), which has symptoms that include fever, alter consciousness, and muscular rigidity.

HEALTH EFFECTS OR RISKS FROM EXPOSURE (An explanation in lay terms).

ACUTE: The most significant route of exposure anticipated for this product is injection. Exposure to this material via injection can cause nausea, diarrhea, change in the frequency of urination, visual disturbances, rashes, breathing difficulties. Disorders involving the muscular system, liver, kidneys, heart, blood vessels, stomach and bowels may be experienced after injection. Ingestion may produce exposure symptoms similar to injection. Though not documented, exposure to this material via other routes of entry may produce symptoms similar to injection.

CHRONIC: This material is not known to cause cancer, though chronic exposures to this material increases the amount of prolactin in the body. Studies suggest that increased prolactin levels may make an individual more susceptible to breast cancer. Studies also indicate that this substance does not cause reproductive harm or fetotoxic effects. Metoclopramide hydrochloride is excreted in human milk.

HAZARDOUS MATERIAL INFORMATION SYSTEM			
HEALTH ^(BLUE)			3
FLAMMABILITY ^(RED)			0
REACTIVITY ^(YELLOW)			0
PROTECTIVE EQUIPMENT			
EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		
For medical use only			

PART II *What should I do if a hazardous situation occurs?*

4. FIRST-AID MEASURES

If spilled on skin, immediately wash the affected area with soap and water and rinse with running water for at least 15 minutes. Remove exposed or contaminated clothing, taking care not to contaminate eyes. If the product is splashed in eyes, open victim's eyes while under gentle running water. Use sufficient force to open eye lids. Have victim "roll" eyes. Minimum flushing should be 15 minutes. If the product is inhaled, remove victim to fresh air and use artificial respiration to support vital functions. Remove or cover gross contamination to avoid exposure to rescuers. Victim and rescuers should obtain medical attention, if appropriate.

If the product is swallowed, rinse victim's mouth and CALL a PHYSICIAN OR a POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, DO NOT induce vomiting. Victim(s) of contamination with this product and all rescuers should be taken for medical attention, if appropriate. Take copy of label and MSDS to physician or health professional with victim.

5. FIRE-FIGHTING MEASURES

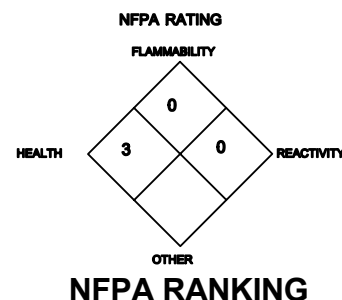
FLASH POINT, °C (method): Not applicable.
AUTOIGNITION TEMPERATURE, °C: Not applicable.
FLAMMABLE LIMITS (in air by volume, %): Lower: Not applicable.
Upper: Not applicable.

FIRE EXTINGUISHING MATERIALS: The size and nature of this product is such that it will not contribute to the intensity of a fire. Fire fighting should be aimed at surrounding materials.

Water Spray: OK Carbon Dioxide: OK
Foam: OK Dry Chemical: OK Halon: OK

SPECIAL FIRE FIGHTING PROCEDURES: Incipient fire responders should wear eye protection. Structural fire fighters must wear self-contained breathing apparatus and full protective equipment.

UNUSUAL FIRE and EXPLOSION HAZARDS: When heated to decomposition, this product may emit toxic fumes containing hydrogen chloride, oxides of nitrogen, and carbon monoxide.



6. ACCIDENTAL RELEASE MEASURES

SPILL and LEAK RESPONSE: For small releases of this product (i.e. one vial, 2 mL) wear latex or nitrile gloves and safety glasses. Absorb spilled liquid with polypads or other appropriate materials. Avoid splashing or spraying liquid. Rinse area thoroughly with soap and water.

Large or uncontrolled releases (i.e. 1000 mL) should be responded to by trained personnel using pre-planned procedures. Proper protective equipment should be used. In case of a spill, clear the affected area, protect people, and respond with trained personnel. Absorb spilled liquid with polypads or other appropriate materials. Avoid splashing or spraying liquid. Rinse area thoroughly with soap and water. Place all spill residue in a double plastic bag.

PART III *How can I prevent hazardous situations from occurring?*

7. HANDLING and STORAGE

WORK PRACTICES and HYGIENE PRACTICES: As with all chemicals, avoid getting this material ON YOU or IN YOU. Wash hands after handling this product. Avoid breathing sprays or mists of this product. Do not eat or drink while handling this product. Wash hands thoroughly after handling this product or equipment and containers which contain this product. Follow SPECIFIC USE INSTRUCTIONS supplied with product.

STORAGE and HANDLING PRACTICES: Store product in original container at 15 - 30°C. Do not permit material to freeze. Protect the solution from light.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear gloves (double-gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. All needles, syringes, vials, and other disposable items contaminated with this product should be disposed of properly.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

VENTILATION and ENGINEERING CONTROLS: Use with adequate ventilation. Follow standard medical product handling procedures.

RESPIRATORY PROTECTION: None required under routine conditions of use.

EYE PROTECTION: Safety glasses.

HAND PROTECTION: Use latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands after removing gloves.

BODY PROTECTION: Routine medical clothing, such as lab coat, gown, or smock, should be worn when preparing or handling this product.

Product Preparation Instructions for Medical Personnel: Handle this material following standard medical practices and follow the recommendations presented on the Package Insert.

9. PHYSICAL and CHEMICAL PROPERTIES

VAPOR DENSITY: Not available.

EVAPORATION RATE (water=1): Approx. 1.

SPECIFIC GRAVITY: Approx. 1 @20°C

MELTING POINT or RANGE: Approx. 0 °C

SOLUBILITY IN WATER: Completely.

BOILING POINT: Approx. 100 °C.

VAPOR PRESSURE, mm Hg @ 25°C: Not available. pH: 3.0 - 5.0

APPEARANCE and COLOR: Clear, colorless solution; odorless.

HOW TO DETECT THIS SUBSTANCE (warning properties): The solution has no discernible warning properties.

10. STABILITY and REACTIVITY

STABILITY: Stable when stored under ambient conditions up to the shelf-life of the product. The recommended storage temperature is approximately room temperature, 15-30 °C.

CONDITIONS TO AVOID: Heat may cause product to decompose, destroying the product or producing toxic fumes (i.e. hydrochloric acid, nitrogen oxides, and carbon monoxide).

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is not compatible with strong acids, caustics, and oxidizers.

HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Heat and contact with incompatible chemicals.

PART IV *Is there any other useful information about this material?*

11. TOXICOLOGICAL INFORMATION

TOXICITY DATA: The following toxicity data is available for metoclopramide hydrochloride.

LD₅₀ (oral, rat) 647 mg/kg

LD₅₀ (intraperitoneal, rat) 130 mg/kg

LD₅₀ (subcutaneous, rat) 633 mg/kg

LD₅₀ (intravenous, rat) 42 mg/kg

LD₅₀ (oral, mouse) 335 mg/kg

LD₅₀ (intraperitoneal, mouse) 138 mg/kg

LD₅₀ (subcutaneous, mouse) 223 mg/kg

LD₅₀ (intravenous, mouse) 37 mg/kg

LD₅₀ (intravenous, rabbit) 23 mg/kg

SUSPECTED CANCER AGENT: This products ingredient's are not found on the following lists: FEDERAL OSHA Z LIST, NTP, IARC, CAL/OSHA.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Individuals with the following medical conditions may be more sensitive to exposures involving this material: individuals with a prior history of depression; those with a history of breast cancer; nursing mothers; individuals with conditions involving the kidneys, liver, or gastrointestinal system.

Dermal Exposure: May be irritating to the skin.

Ingestion Exposure: Adverse effects involving the stomach, bowels, kidney, liver.

Inhalation Exposure: No reported inhalation effects.

RECOMMENDATIONS TO PHYSICIANS: Refer to adverse reaction information provided with the product.

12. ECOLOGICAL INFORMATION

ENVIRONMENTAL STABILITY: Based on the size of the product packaging and shipping method, environmental impact is not expected.

EFFECT OF MATERIAL ON PLANTS or ANIMALS: No ecological studies are available.

EFFECT OF CHEMICAL ON AQUATIC LIFE: No information is currently available regarding the potential affect of this material on aquatic life.

13. DISPOSAL CONSIDERATIONS

PREPARING WASTES FOR DISPOSAL: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by the handling, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority.

EPA WASTE NUMBER: Not applicable.

14. TRANSPORTATION INFORMATION

THIS MATERIAL IS NOT HAZARDOUS AS DEFINED BY 49 CFR 172.101 BY THE U.S. DEPARTMENT OF TRANSPORTATION.

PROPER SHIPPING NAME: Not applicable.

HAZARD CLASS NUMBER and DESCRIPTION: Not applicable.

UN IDENTIFICATION NUMBER: Not applicable.

PACKING GROUP: Not applicable.

DOT LABEL(S) REQUIRED: Not applicable.

EMERGENCY RESPONSE GUIDE NUMBER: Not applicable.

RQ: Not applicable.

15. REGULATORY INFORMATION

SARA REPORTING REQUIREMENTS: This components of this product are not subject to the reporting requirements of Section 313 of Title III of the Superfund Amendments and Reauthorization Act.

TSCA INVENTORY STATUS: The components of this product are listed on the TSCA Inventory.

MARINE POLLUTANT: This product contains no component listed as a Marine Pollutant under 49 CFR 172.101, Appendix B.

CALIFORNIA PROPOSITION 65: This product is not on the California Proposition 65 lists.

CERCLA REPORTABLE QUANTITIES (RQ): Not applicable.

STATE REGULATORY INFORMATION: Chemicals in this product are covered under the following specific State regulations (NONE indicates no special regulations were noted.)

Alabama	None.	Montana	None.
Alaska	None.	New Hampshire	None.
California	None.	New Jersey	None.
Connecticut	None.	New York	None.
Delaware	None.	North Dakota	None.
Florida	None.	Oklahoma	None.
Illinois	None.	Oregon	None.
Kansas	None.	Pennsylvania	None.
Maine	None.	Rhode Island	None.
Maryland	None.	Tennessee	None.
Massachusetts	None.	Texas	None.
Michigan	None.	Vermont	None.
Minnesota	None.	Washington	None.
Missouri	None.	Wisconsin	None.
		West Virginia	None.

LABELING (Precautionary Statements): **CAUTION! Federal law prohibits dispensing without prescription.** This material may be harmful if injected into skin or ingested. Inhalation may also be harmful. Contact with the skin or eyes may be irritating. Avoid breathing sprays and mists. Avoid contact with skin and eyes. Avoid accidental injections.

16. OTHER INFORMATION

PREPARED BY: CHEMICAL SAFETY ASSOCIATES, Inc.
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619/565-0302

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