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### Section 1 - Identification

- (a) **Product Identifier:** Metoclopramide Injection, USP
- (b) **NDC:** 83634-779
- Common/Trade Name:** Metoclopramide Injection, REGLAN®
- Chemical Name:** 4-amino-5-chloro-N-[2-(diethylamino)ethyl]-2-methoxy benzamide monohydrochloride monohydrate
- Chemical Family:** Anti-Emetic
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Avenacy 10 N. Martingale Road, Suite 225, Schaumburg, IL 60173, 847-773-4901
- (e) **Emergency Telephone:** 855-283-6229

### Section 2 - Hazards Identification

- (a) **Classification:** Non-hazardous in accordance with international standards for workplace safety.
- EU Indication of Danger:** Not classified.
- Australian Hazard Classification (NOHSC):** Non-hazardous substance. Non-dangerous good.

<b>(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):</b>	<b>(c) Description of Hazards:</b>
<u>Hazard Statements:</u>	Non-hazardous in accordance with international standards for workplace safety.

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<u>Precautionary Statements:</u>	<p><b>Short Term:</b> Accidental ingestion may cause effects similar to those seen in clinical use.</p> <p><b>Known Clinical Effects:</b> Therapeutic use of this substance has resulted in weakness, dizziness, drowsiness, ataxia, confusion, tremors, headache, and gastrointestinal disturbances. As with all antipsychotic agents, tardive dyskinesia may appear. This syndrome is characterized by rhythmical involuntary movements of the tongue, face, mouth, or jaw. Hypersensitivity reactions may also occur in susceptible individuals.</p>
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**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### Section 3 - Composition / Information on Ingredients


(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
Metoclopramide Hydrochloride	Metoclopramide Hydrochloride	5.6079 mg*	54143-57-6	NA
Sodium chloride	Sodium Chloride	8.5 mg	7647-14-5	N/A
Sodium hydroxide	Sodium hydroxide	q.s. to pH	1310-73-2	N/A
Hydrochloric Acid	Hydrochloric Acid	q.s. to pH	7647-01-0	N/A
Water for Injection	Water for Injection	q.s. to 1 mL	7732-18-5	N/A

\*5.6079 mg Metoclopramide Hydrochloride is equivalent to 5 mg of Metoclopramide base.

### Section 4 - First Aid Measures

**Eye Exposure:** If irritation occurs or persists, get medical attention. Rinse thoroughly with plenty of water, also under the eyelids.

**Skin Exposure:** Wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance if irritation occurs.

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**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Due to the nature of this material first aid is not normally required.

### Section 5 - Fire-fighting Measures

- (a) **Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.
- (b) **Hazardous Combustion Products:** May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.
- (c) **Special Protective Equipment / Precautions:** During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
- (d) **Fire / Explosion Hazards:** Not applicable

### Section 6 - Accidental Release Measures


**Personal precautions, protective equipment and emergency procedures:** **Spill Cleanup and Disposal:** Absorb with suitable material and clean area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

### Section 7 - Handling and Storage

**General Handling:** Protect from light by retaining in carton until ready to use.

**Storage Conditions:** No special storage required for hazard control. For product protection, store at controlled room temperature 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F).

**Special Precautions:** Protect from freezing, light, and extreme heat.

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**Section 8 - Exposure Controls / Personal Protection**

**(a) Exposure Limits:**

Refer to available public information for specific member state Occupational Exposure Limits.

**(b) Engineering Controls**

Engineering controls should be used as the primary means to control exposures.

**(c) Environmental Exposure Controls:**


Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**(d) Individual Protection Measures**

<b>Respiratory Protection:</b>	Not required for the normal use of this product. Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.
<b>Eye Protection:</b>	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
<b>Skin Protection:</b>	Not required for the normal use of this product. Wear protective clothing when working with large quantities.
<b>Other Protective Equipment:</b>	Wear protective gloves when working with large quantities.

**Section 9 - Physical and Chemical Properties**

<b>(a) Appearance</b>	Clear colorless, aqueous solution
<b>(b) Odor</b>	N/A
<b>(c) Odor Threshold</b>	N/A
<b>(d) pH</b>	2.5 to 6.5
<b>(e) Melting Point:</b>	N/A
<b>(f) Initial Boiling Point:</b>	N/A
<b>(g) Flash Point</b>	N/A
<b>(h) Evaporation Rate:</b>	N/A
<b>(i) Flammability</b>	N/A

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(j)	<b>Upper Lower Flammability or Explosion Limits</b>	N/A
(k)	<b>Vapor Pressure:</b>	N/A
(l)	<b>Vapor Density:</b>	N/A
(m)	<b>Relative Density</b>	N/A
(n)	<b>Solubility(ies)</b>	N/A
(o)	<b>Partition Coefficient: n-octanol/water</b>	N/A
(p)	<b>Auto-ignition Temperature</b>	N/A
(q)	<b>Decomposition Temperature</b>	N/A
(r)	<b>Viscosity</b>	N/A

### Section 10 - Stability and Reactivity

(a)	<b>Reactivity</b>	Not classified as a reactivity hazard.
(b)	<b>Chemical Stability</b>	Stable under normal conditions of use.
(c)	<b>Possibility of Hazardous Reactions</b>	None known.
(d)	<b>Conditions to Avoid</b>	None known.
(e)	<b>Incompatible Materials</b>	As a precautionary measure, keep away from strong oxidizers.
(f)	<b>Hazardous Decomposition Products</b>	No hazardous decomposition products are known.

### Section 11 - Toxicological Information


**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

**Acute Toxicity:**

<b>Ingredient</b>	<b>Test Type</b>	<b>Route</b>	<b>Value</b>	<b>Species</b>
Metoclopramide	LD50	Oral	750 mg/kg	Rat

**Reproductive and Developmental Toxicity:**

<b>Study Type</b>	<b>Species</b>	<b>Route</b>	<b>Value</b>	<b>End Point</b>	<b>Effect(s)</b>
Embryo / Fetal Development	Rat	Oral	10 mg/kg/day	NOEL	Not teratogenic
Embryo / Fetal	Rabbit	Oral	10 mg/kg/day	NOEL	Not teratogenic

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Development					
Embryo / Fetal Development	Mouse	Oral	10 mg/kg/day	NOEL	Not teratogenic
Embryo / Fetal Development	Rabbit	Intravenous	10 mg/kg	NOEL	Not teratogenic

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP, or OSHA.

### Section 12 - Ecological Information

(a)	<b>Ecotoxicity</b>	No applicable ecological information found.
(b)	<b>Persistence and degradability</b>	No applicable ecological information found.
(c)	<b>Bioaccumulative potential</b>	No applicable ecological information found.
(d)	<b>Mobility in soil</b>	No applicable ecological information found.
(e)	<b>Other Adverse Effects</b>	No applicable ecological information found.

### Section 13 - Disposal Considerations

**Waste Disposal:**

Disposal should be performed in accordance with the federal, state, or local regulatory requirements.

**Contaminated packaging / handling and disposal**

Dispose of container and unused contents in accordance with federal, state, and local regulations.

### Section 14 - Transport Information


**DOT:** Not Regulated

### Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Avenacy usage. 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. Regulations:**

TSCA – Not regulated  
 CERCLA - Not regulated  
 SARA - Not regulated

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RCRA – Not regulated  
US PROP 65 (Calif.) – Not regulated

### Section 16 - Other Information


As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Avenacy  
10 N. Martingale Road, Suite 225  
Schaumburg, IL 60173  
847-773-4901

**Glossary:** This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer

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ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System