

SAFETY DATA SHEETS

This SDS packet was issued with item:

078935860

N/A

Safety Data Sheet

1. Product and Company Identification

Product Name: Metoclopramide Oral Solution, USP
Trade Name & Synonyms: None
Date of Last Revision: June 10, 2015
Ingredient: Metoclopramide Hydrochloride
Chemical Name: 4-amino-5-chloro-*N*-[2-(diethylamino)ethyl]-*o*-anisamide monohydrochloride monohydrate
Manufacturer: ANI Pharmaceuticals, Inc.
Address: 210 West Main Street, Baudette, Minnesota 56623
Telephone Number: 218.634.3500

2. Hazards Identification

Emergency Overview

The potential for exposure is reduced in finished pharmaceutical form. However, effects of exposure may include high/low blood pressure, irregular heartbeat, allergic reactions, Methemoglobinemia and DNA damage.

Signs and symptoms of overexposure include metoclopramide-restlessness, drowsiness, fatigue, weariness, insomnia, headache, confusion, dizziness, mental depression, endocrine disturbances, nausea, bowel disturbances (diarrhea), loss of bladder control, disorientation, muscle spasms, incoordination, rash, welts, difficulty breathing.

3. Composition/Information on Ingredients

<u>Hazardous Components</u>	<u>C.A.S. Number</u>	<u>Exposure Limits %</u>	<u>Hazardous</u>
Metoclopramide HCl	7232-21-5	None established	Yes
Saccharin Sodium	128-44-9	None established	No
Methylparaben	99-76-3	None established	Yes
Propylparaben	94-13-3	None established	Yes
Citric Acid Anhydrous	77-92-9	None established	Yes
FD & C yellow No 5	1934-21-0	None established	No
FD & C Red No 40	25956-17-6	None established	No
Purified Water	7732-18-5	None established	No
French Vanilla Flavor	N/A	None established	No

4. First Aid Measures

Routes of Exposure First Aid Instructions

Eye:

Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Obtain medical attention immediately.

Skin:

Immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing. Wash clothing before reuse.

Inhalation:

Remove to fresh air. If not breathing is difficult, give CPR. If breathing is difficult, give oxygen. Call a physician.

Ingestion:

Immediately give two glasses of water and induce vomiting. Never give anything to an unconscious person. Obtain medical attention in all cases. Note to Physician: Metoclopramide is used clinically as an antiemetic, dopamine-receptor antagonist.

Aggravation of Pre-existing conditions:

Asthma

5. Fire Fighting Measures

Fire:

Non-flammable liquid.

Explosion:

Not considered to be an explosion hazard.

Fire Extinguishing Media:

Water spray, carbon dioxide, dry chemical, or foam.

Special Information:

None

Unusual Fire And Explosion Hazards:

As with any organic compound, this material may produce toxic carbon monoxide and carbon dioxide fumes if heated to decomposition (as under fire conditions). Wear self contained breathing apparatus and full protective equipment. Evacuate area and keep personnel removed and upwind.

6. Accidental Release Measures

Metoclopramide Bulk Material Spill Release Procedures:

Use protective equipment, sweep/wipe up and containerize spill material in a compatible container. Dispose according to applicable regulations. Incineration of the waste must be performed at an approved facility.

7. Handling and Storage

Store at 20°C to 25°C (68°F to 77°F) [See USP controlled room temperature.] Protect from freezing. Keep bottles tightly closed.

8. Exposure Control/Personal Protection

Engineering Controls: None needed for finished product handling.

Personal Protective Equipment: Wear appropriate NIOSH/MSHA approved air purifying respirator/positive pressure air supplied respirator in situations where a respirator is judged appropriate to prevent inhalation of vapor/mist.

Skin Protection:

Wear protective gloves and clean body-covering clothing (impervious clothing such as apron, boots, Tyvek® suit).

Eye Protection:

Use chemical safety goggles or safety glasses with full face protection. Maintain eye wash fountain and quick drench facilities in work area.

Work Hygienic Practices:

Remove / launder contaminated clothing before reuse. Wash thoroughly after handling.

Supplemental Safety and Health:

Treat symptomatically and supportively. To control extrapyramidal reactions, anticholinergic / antiparkinsonian drugs / antihistamines with anticholinergic properties may be helpful. PH 2-5.5.

9. Physical and Chemical Properties

Appearance:

Orange-colored,

Odor:

Aromatic

Solubility:

Soluble in water

Density:

Not available

pH:

Not available

% volatile by volume @70F:

Not available

Boiling Point:

Not available

Melting Point:

Not available

Vapor Pressure (mmg Hg):

Not available

10. Stability and Reactivity

Stability Indicator:

Yes

Stability Conditions To Avoid:

Exposure to Light, heat and freezing

Hazardous Polymerization Indicator:

No

Incompatibility:

Strong Oxidizers

11. Toxicological Information

LD 50 LC 50 Mixtures: ORAL LD50 (RAT): 760 MG/KG

Route of Entry Inds – Inhalation: No

Skin: No

Ingestion: No

Carcinogenicity Inds – NTP: No

IARC: No

OSHA: No

Explanation of carcinogenicity: None

12. Ecological Information

Environmental properties have not been investigated. Release to the environment should be avoided.

Aquatic Toxicity: Not determined for product

Persistence/Biodegradability: Not determined for product

Bioaccumulation: Not determined for product

Mobility in Soil: Not determined for product.

13. Disposal Considerations

Waste Disposal: All waste materials must be properly characterized. Further, disposal should be performed in accordance with federal, state or local regulatory requirements.

Container Handling and Disposal: Dispose of container and unused contents in accordance with with federal, state or local regulatory requirements.

14. Transport Information

The known properties of this mixture do not constitute a hazard as defined by the U.S. Department of Transportation.

15. Regulatory Information

Federal Regulations (OSHA, FDA):

OSHA Label

Non-hazardous in accordance with international standards for workplace safety.

FDA

NDC 62559-110-16, Metoclopramide Oral Solution (5mg of Metoclopramide Base/5mL) – 16 ounce

16. Other Information

See package insert for complete instructions and precautions.

Date: June 10, 2015

ANI Pharmaceuticals, Inc. 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. ANI Pharmaceuticals, Inc. makes no representations or warranties either expressed 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, ANI Pharmaceuticals, Inc. will not be responsible for damages resulting from the use of or reliance upon this information.