

Material Safety Data Sheet ANSI Format

Reglan Intravenous

Preparation Date 20-Nov-2006 Revision Date Not applicable Revision Number Not applicable

1. PRODUCT AND COMPANY IDENTIFICATION

Product NameReglan IntravenousCommon NameNot availableChemical NameNot applicable

Synonyms Metoclopramide HCl, Metoclopramide Injection

Product UsePharmaceutical productClassificationGastrointestinal Prokinetic Agent

Supplier Wyeth

P.O. Box 8299

Philadelphia, PA 19101 USA. Telephone: 1-610-688-4400

Emergency Telephone Number Chemtrec USA, Puerto Rico, Canada 1-800-424-9300

Chemtrec International 1-703-527-3887

2. HAZARDS IDENTIFICATION

Emergency Overview

This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

Appearance Biopharmaceutical liquidPhysical State LiquidOdor Not available

Potential Physical Hazards None known

Potential Health Effects

Eyes May cause eye irritation. **Skin** May cause skin irritation.

Inhalation May cause mucous membrane and upper respiratory tract irritation.

Ingestion Not available

Other The most common effects may include mental depression, extrapyramidal symptoms

(involuntary movements of the limbs, facial grimancing, torticollis, oculogyric crisis, rhythmic protrusion of the tongue, bulbar type of speech, trismus, tetanus), laryngospasm, and

Parkinsonian-like symptoms.

May cause harm to breastfed babies.

Please see Patient Package Insert for further information.

Therapeutic Target Organ(s) Gastrointestinal system.

Not listed by OSHA, NTP or IARC.

Potential Environmental Effects There is no known ecological information for this product.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Metoclopramide	54143-57-6	5 mg/ml
Inactive Ingredients	Not applicable	.? mg/tablet

4. FIRST AID MEASURES

Eye Contact In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek

medical advice.

Skin Contact Take off contaminated clothing and shoes immediately. Wash off immediately with soap and

plenty of water. If skin irritation persists, call a physician.

Inhalation Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist,

call a physician.

Ingestion If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never

give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Flammable Properties Presumed to be a combustible particulate solid.

Extinguishing Media

Suitable Extinguishing Media

Unsuitable Extinguishing

Media

Use water spray, foam, dry chemical or carbon dioxide.

Do NOT use water jet.

Fire Fighting Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with

water spray. In the event of fire and/or explosion do not breathe fumes.

Hazardous Combustion Products Carbon oxides, nitrogen oxides.

Protective Equipment and Precautions for Firefighters

In the event of fire, wear self-contained breathing apparatus and special protective equipment

for fire fighters.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions Refer to protective measures listed in Sections 7 and 8.

Environmental Precautions Prevent product from entering drains. Local authorities should be advised if a significant spill

cannot be contained.

Methods for Containment Not available

Methods for Cleaning up Take up mechanically and collect in suitable container for disposal. Clean contaminated

surface thoroughly. Avoid formation of dust and aerosols.

7. HANDLING AND STORAGE

Handling For personal protection see Section 8. Handle in accordance with good industrial hygiene and

safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.

Storage No special safety precautions required. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering ControlsNo special precautions required.

Personal Protective Equipment

Eye/face ProtectionProvide eye protection based on risk assessment.Skin ProtectionWear nitrile or latex gloves. Wear protective garment.Respiratory ProtectionBase respirator selection on a risk assessment.

General Hygiene Considerations

When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands

before breaks and at the end of workday.

Other Limit access to only personnel trained in the safe handling of this material. Consult a health

and safety professional for specific PPE, respirator, and risk assessment guidance.

Lower Not applicable

9. PHYSICAL AND CHEMICAL PROPERTIES

AppearanceBiopharmaceutical liquidPhysical StateLiquidColorClearOdorNot available

Odor Threshold Not available

pH 4.5 - 6.5

Specific GravityNot availableWater SolubilityNot availableSolubilityNot applicableEvaporation RateNot availablePartition CoefficientNot availableVapor DensityNot available

Partition Coefficient (n-octanol/water)

Vapor Pressure Not applicable

Boiling PointNot availableAutoignition TemperatureNot applicableFlash PointNot applicableMethodNone

Melting Point Not applicable

Not applicable

Flammability Limits Upper Not applicable

in Air

Explosion Limits Upper Not applicable Lower Not applicable

10. STABILITY AND REACTIVITY

Chemical Stability Stable at room temperature.

Conditions to Avoid No data available

Materials to Avoid No materials to be especially mentioned.

Hazardous Decomposition Products None under normal use.

Possibility of Hazardous Reactions None under normal use.

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Metoclopramide

LD50 Oral 465 mg/kg mice

760 mg/kg rats

870 mg/kg rabbits

Acute Dermal Irritation
Primary Eye Irritation

Not applicable Not applicable

Primary Eye Irritati Sensitization

Not applicable

Multiple Dose Toxicity

Metoclopramide

No Toxicologic Effect

See Carcinogenicity

Dose/Species/Study Length:

Maximum Tolerated Dose (MTD), Oral

Metoclopramide

Carcinogenicity Chronic oral toxicity study in rats revealed an evidence of mammary tumors due to the

prolactin stimulating no evidence of similar effects in humans.

Genetic Toxicity Not mutagenic in AMES Test.

Reproductive Toxicity Studies in rats, mice, and rabbits have shown no evidence of impaired fertility or harm to the

fetus.

Developmental Toxicity See Reproductive Toxicity

Metoclopramide

Target Organ(s) of Toxicity No data available

12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information Not available

Not available **Ecotoxicity**

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method Dispose of in accordance with local and national regulations.

14. TRANSPORT INFORMATION

Transport Information This material is not classified as hazardous for transport.

U.S. Department of Transport (DOT) Not regulated **Canadian Transport of Dangerous Goods (TDG)** Not regulated International Civil Aviation Organization (ICAO) Not regulated International Air Transport Association (IATA) Not regulated International Maritime Dangerous Goods (IMDG)/International Not regulated

Maritime Organization (IMO)

Transport of Dangerous Goods by Rail (RID) Not regulated Transport of Dangerous Goods by Road (ADR) Not regulated Transportation of Dangerous Goods via Inland Waterways Not regulated

(ADN)

15. REGULATORY INFORMATION

USA

Federal Regulations

OSHA Regulatory Status

This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40n of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazardous Categorization

Acute Health Hazard No **Chronic Health Hazard** No Fire Hazard No **Sudden Release of Pressure Hazard** No **Reactive Hazard** No

This product does not contain any HAPs..

State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

Canada

Not classified

WHMIS Hazard Class

Non-controlled

European Union

In accordance with EC directives or respective national laws, the product does not need to be classified nor labeled.

16. OTHER INFORMATION

Prepared By Wyeth Department of Environment, Health & Safety

Format This MSDS was prepared in accordance with ANSI Z400.1-2004.

List of References See Patient Package Insert for more information.

Revision Summary Not applicable

Disclaimer:

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End of MSDS