

# Safety Data Sheet

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## 1. Identification of the substance/preparation and the company/undertaking

### GHS product identifier

Product name: Metoclopramide Oral Solution, USP

### Other means of identification

Product code(s): 0121-0576-16 0121-1576-10

UN-Number: NA

Synonyms: Compare to Reglan®

### Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical product used as a gastric motility regulator

Uses advised against: Do not use except as prescribed.

### Supplier address/information

Pharmaceutical Associates, Inc.  
201 Delaware Street  
Greenville, SC 29605 (864) 277 -7282

Emergency telephone number: CHEMTREC 800.424.9300

## 2. Hazards Identification

### Classification

This product is a mixture and is a pharmaceutical product. It is considered non-Hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

### Chemical family:

Mixture

### Statement of Hazard:

May be harmful if swallowed. May cause central nervous system effects.

### Additional Hazard Information:

#### Short term:

Metoclopramide produces sedation and may produce extrapyramidal reactions, although these are comparatively rare. It may be associated with transient fluid retention.

#### Long term:

Treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible. The risk of developing tardive dyskinesia increases with duration of treatment and total cumulative dose.

### EU Indication of danger:

Not classified.

### Emergency overview

Seek medical attention in case of accidental exposure or overdose. The product is generally safe when used as prescribed.

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 of exposure in your workplace.

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## Precautionary statements

General advice: Seek medical attention in case of accidental exposure or overdose.

Eyes: Avoid contact with eyes.

Skin Contact: Avoid skin contact.

Inhalation: Not intended for inhalation.

Ingestion: Generally safe at recommended doses. In case of overdose, seek medical attention immediately.

Storage: There are no special storage conditions for safety. For product integrity, store under conditions specified on the label.

Disposal: Dispose of in accordance with applicable laws and regulations.

## 3. Composition/Information on ingredients

Chemical name	CAS-No	mg/5mL	Trade Secret
Metoclopramide	7232-21-5	5 mg/5mL (base)	
Citric Acid Anhydrous	77-92-9		X
Methylparaben	99-76-3		X
Propylparaben	94-13-3		X
Glycerin	56-81-5		X
Sorbitol Solution	Mixture		X
Berry Flavor	Mixture		X
FD&C Yellow No. 6	2783-94-0		X

## 4. First aid measures

### Description of necessary first-aid measures

Eye contact:  
Flush with running water for 15 minutes holding eyelids open. Contact medical personnel if irritation persists.

Skin contact:  
Wash contaminated area thoroughly. If irritation persists, contact medical personnel.

Inhalation:  
Remove to fresh air and contact medical personnel.

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Ingestion:

Overdosage or accidental ingestion Contact medical personnel or poison control immediately if overdosage is suspected.

## Most important symptoms/effects, acute and delayed

Overdosage drowsiness, disorientation and extrapyramidal reactions

## Indication of immediate medical attention and special treatment needed, if necessary

Immediate medical attention is required if overdose is suspected.

Notes to Physician: NA

## 5. Fire-fighting measures

<b>Suitable extinguishing media:</b>	Use carbon dioxide, dry chemical or water spray.
<b>Specific hazards arising from the chemical</b>	May burn emitting oxides of chlorine and nitrogen.
<b>Explosion data:</b>	Not applicable
<b>Protective equipment and precautions for firefighters</b>	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (See Section 8). Minimize exposure.
<b>Environmental precautions</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Methods and materials for containment and cleaning up</b>	
<ul style="list-style-type: none"><li>• Methods for containment:</li><li>• Methods for cleaning up:</li></ul>	Isolate area around spill as specified by site procedures. Absorb the liquid with suitable material. Dispose of spill material in accordance with applicable federal, state or local regulations.

## 7. Handling and storage

### Precautions for safe handling

Handling: No special handling required for hazard control under conditions of normal product use.

### Conditions for safe storage, including any incompatibilities

Storage: No special storage required for hazard control. For product protection, follow storage recommendations on the case label, primary product label and insert.

Incompatible products: As a precautionary measure, keep away from strong oxidizers.

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## 8. Exposure controls/personal protection

### Control parameters

Exposure guidelines: The exposure guidelines listed below are for the individual components and not the product itself.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Metoclopramide	Not Available	Not Available	Not Available
Citric Acid Anhydrous	10 mg.m <sup>3</sup> TWA	15 mg/m <sup>3</sup> TWA	Not Available
Methylparaben	Not Available	Not Available	Not Available
Propylparaben	Not Available	Not Available	Not Available
Glycerin	10 mg.m <sup>3</sup> TWA	10 mg.m <sup>3</sup> TWA	Not Available
Sorbitol Solution	Not Available	Not Available	Not Available
Berry Flavor	Not Available	Not Available	Not Available
FD&C Yellow No. 6	Not Available	Not Available	Not Available

### Appropriate engineering controls

Engineering measures: Engineering controls should be used to limit exposure.

### Individual protection measures, such as personal protective equipment

Eye/face protection: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin and body protection: Not required under normal conditions of use. Wear protective clothing when working with large quantities.

Respiratory protection: Not required under normal use of the product. If the applicable PEL (Permissible Exposure Limit) is exceeded use an appropriate respirator.

Hygiene measures: Wash hands thoroughly after use.

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

Physical state: Solution  
Odor: Berry  
Appearance: Clear orange liquid  
Odor threshold: Not available

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Property	Values	Remarks/Method
pH	2.0 – 5.5	Current USP
Melting point/range	Not applicable	
Boiling point/boiling range	Not available	
Flash point	Not applicable	
Evaporation rate	Not applicable	
Flammability (solid, gas)	Not applicable	
Flammability limits in air	Not applicable	
-upper flammability limit	Not applicable	
-lower flammability limit	Not applicable	
Vapor pressure	Not applicable	
Vapor density	Not applicable	
Specific gravity	1.2	Current USP
Water solubility	Not applicable	
Solubility in other solvents	Not applicable	
Partition coefficient: n-octanol/water	Not applicable	
Autoignition temperature	Not applicable	
Decomposition temperature	Not applicable	
Viscosity	Not available	
Flammable properties	Not applicable	
Explosive properties	Not applicable	
Oxidizing properties	Not applicable	

**Other information** VOC content (%) Not applicable

## 10. Stability and reactivity

**Reactivity** Stable at normal conditions

**Chemical stability** Stable at normal conditions

**Possibility of hazardous reactions** Stable at normal conditions

**Conditions to avoid** None known

**Incompatible materials** As a precautionary measure, keep away from strong oxidizers.

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Hazardous decomposition products None known

## 11. Toxicological information

### Information on likely routes of exposure

Product information:

- Inhalation: Not Available
- Eye contact: Not Available
- Skin contact: Not Available
- Ingestion: Not Available

The information in the table below is for the individual components and not the product.

Chemical name	LD50 oral	LD50 dermal	LC50 inhalation
Metoclopramide	750 mg/kg Rat	Not Available	Not Available
Citric Acid	5400 mg/kg Rat	>2000 mg/kg Rat	Not Available
Methylparaben	2100 mg/kg rat	No skin irritation 24 hr Rabbit	Not Available
Propylparaben	>5000 mg/kg Rat	Not Available	Not Available
Glycerin	12600 mg/kg Rat	10000 mg/kg Rabbit	Not Available
Sorbitol Solution	Not Available	Not Available	Not Available
Berry Flavor	Not available	Not Available	Not Available
FD&C Yellow No. 6	>10000mg/kg Rat	>10000 mg/kg Rabbit	Not Available

### Symptoms related to the physical, chemical and toxicological characteristics

No data available

Delayed and immediate effects and also chronic effects from short and long term exposure

- Sensitization: No data available
- Mutagenic effects: No data available
- Carcinogenicity: Not carcinogenetic
- Reproductive toxicity: No data available
- STOT – single exposure: No data available
- STOT – repeated exposure: No data available
- Aspiration hazard: No data available

### Numerical measures of toxicity – product

- No data available

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## 12. Ecological information

### Ecotoxicity

Environmental properties have not been thoroughly evaluated. Releases to the environment should be avoided.

### Persistence and Degradability

No data available

### Bioaccumulation

No data available

### Other adverse effects:

No data available.

The following table lists the data for the individual components, if available.

Chemical name	Toxicity to algae	Toxicity to fish	Toxicity to micro-organisms	Daphnia Magna (water flea)
Metoclopramide	Not Available	Not Available	Not Available	Not Available
Citric Acid Anhydrous	Not Available	440 mg/L 48 hr Leuciscus idus melanotus	Not Available	1535 mg/L 24 hr.
Methylparaben	91 mg/L 72 hr Pseudokirchneriella Subcapitata	59.5 mg/L 96 hr Oryzias latipes	Not Available	41.1 mg/L 48 hr
Propylparaben	7.6 mg/L 72 hr Pseudokirchneriella Subcapitata	6.4 mg/L 96 h Danio rerio	Not Available	15.4 mg/L 72 hr.
Glycerin	Not Available	58.5 ppm 96 hr. Trout	Not Available	Not Available
Sorbitol Solution	Not Available	Not Available	Not Available	Not Available
FD&C Yellow No. 6	Not Available	Not Available	Not Available	Not Available
Berry Flavor	Not Available	Not Available	Not Available	Not Available

## 13. Disposal considerations

### Waste disposal methods

Dispose of waste in accordance with all federal, state and local regulations.

### Contaminated packaging

Dispose of waste in accordance with all federal, state and local regulations.

## 14. Transport information

### Notes:

Not regulated for transport under USDOT, IATA, TDG, IMDG or other regulations.

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## 15. Regulatory information

### International inventories

#### Legend

##### TSCA:

United States Toxic Substances Control Act 8(b) inventory not applicable for product. The following components are included on the inventory: Citric Acid, Methylparaben, Propylparaben, Glycerin and FD&C Yellow No. 6

##### EINECS:

The EINECS inventory includes: Metoclopramide, Citric Acid, Methylparaben, Propylparaben, FD&C Yellow No. 6 and Glycerin

##### U.S. Federal regulations:

Not Applicable

##### SARA 311/312 Hazard categories:

Not Applicable

##### Clean Water Act

This product **does not** contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

##### CERCLA:

No components listed.

##### California Proposition 65:

This product does not contain any chemicals listed in Proposition 65.

### U.S. state Right-to-Know regulations

“X” designates that the ingredients are listed on the state Right-to-Know list

Chemical name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
Metoclopramide	X		X		
Citric Acid Anhydrous	X		X		
Methylparaben	X		X		
Propylparaben	X		X		
Sorbitol Solution	X		X		
Glycerin	X	X	X	X	X
FD&C Yellow No. 6					
Berry Flavor					

##### U.S. EPA label information:

Not applicable



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## 16. Other information

Prepared by:	Pharmaceutical Associates Regulatory Affairs	Department
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Revision note:	NA	

### General Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

**End of Safety Data Sheet**