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.
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

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

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.
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

Suitable extinguishing media: Use carbon dioxide, dry chemical or water spray.

Specific hazards arising from the chemical May burn emitting oxides of chlorine and nitrogen.

Explosion data: Not applicable

Protective equipment and precautions for firefighters During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Personnel involved in clean-up should wear appropriate personal protective equipment (See Section 8). Minimize exposure.

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and materials for containment and cleaning up
- Methods for containment: Isolate area around spill as specified by site procedures.
- Methods for cleaning up: 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.
8. Exposure controls/personal protection

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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH IDLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metoclopramide</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td>Citric Acid Anhydrous</td>
<td>10 mg.m⁻³ TWA</td>
<td>15 mg/m³ TWA</td>
<td>Not Available</td>
</tr>
<tr>
<td>Methylparaben</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td>Propylparaben</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td>Glycerin</td>
<td>10 mg.m⁻³ TWA</td>
<td>10 mg.m⁻³ TWA</td>
<td>Not Available</td>
</tr>
<tr>
<td>Sorbitol Solution</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td>Berry Flavor</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td>FD&amp;C Yellow No. 6</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
</tbody>
</table>

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
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.
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.

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

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
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.

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

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.
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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>Pennsylvania</th>
<th>Illinois</th>
<th>Rhode Island</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metoclopramide</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Citric Acid Anhydrous</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methylparaben</td>
<td>X</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Propylparaben</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sorbitol Solution</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glycerin</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td>X</td>
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<td>FD&amp;C Yellow No. 6</td>
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<tr>
<td>Berry Flavor</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

U.S. EPA label information:
Not applicable
Safety Data Sheet

16. Other information
Prepared by: Pharmaceutical Associates Regulatory Affairs Department
Issuing date: 03/02/2015
Revision date: NA
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