

# Safety Data Sheet

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

### GHS product identifier

Product name: Milk of Magnesia Concentrate

### Other means of identification

Product code(s): 0121-0940-10; 0121-0940-00

UN-Number: NA

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

Recommended use: Pharmaceutical product used as an Antacid and as a Laxative

Uses advised against: Do not use except as prescribed.

### Supplier address/information

Pharmaceutical Associates, Inc.  
1700 Perimeter Road  
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:** Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

### Additional Hazard Information:

**Short term:** Not available

**Long term:** Not available.

**Known Clinical Effects:** Not available

**EU Indication of danger:** Not classified.

### Health Hazard:

Type	Category
Not Applicable	Not Applicable

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## Label elements

### Emergency Overview

#### Danger

#### Hazard statements

None/Not Applicable

This mixture is a drug product regulated by the FDA. Within the meaning of the OSHA Hazard Communication Standard [29 CFR 1910.1200]: this mixture is not considered a hazard when used in a manner which is consistent with the labeled directions.

**Appearance:** White, Opaque suspension which may separate on standing      **Physical state:** Liquid      **Odor:** Lemon

## 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.

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.

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## 3. Composition/Information on ingredients

Chemical name	CAS-No	Weight mg	Trade Secret
Magnesium Hydroxide Gel	Mixture	2400mg/10 mL	
Methocel (Hypromellose)	9004-65-3		X
Sodium Citrate Dihydrate	6132-04-3		X
Sucrose	57-50-1		X
Propylene Glycol	57-55-6		X
Methylparaben	99-76-3		X
Propylparaben	94-13-3		X
Glycerin	56-81-5		X
Sorbitol Solution	Mixture		X
Sodium Saccharin	6155-57-3		X
Premium Lemon Flavor	Mixture		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.

#### Ingestion:

The product is intended for ingestion. In the case of accidental ingestion or overdose, contact medical personnel.

### Most important symptoms/effects, acute and delayed

No data available

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

No data available

Notes to Physician: NA

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## 5. Fire-fighting measures

Suitable extinguishing media:	Use carbon dioxide, dry chemical or water spray.
Specific hazards arising from the chemical	Not applicable.
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	
<ul style="list-style-type: none"><li>Methods for containment:</li><li>Methods for cleaning up:</li></ul>	<p>Isolate area around spill as specified by site procedures.</p> <p>Absorb the liquid with suitable material. Dispose of spill material in accordance with applicable federal, state or local regulations.</p>

## 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.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Magnesium Hydroxide Gel	Not Available	Not Available	Not Available
Methocel (Hypromellose)	Not Available	10 mg/m <sup>3</sup> TWA	Not Available
Sodium Citrate Dihydrate	Not Available	Not Available	Not Available
Sucrose	10 mg/m <sup>3</sup>	5 mg/m <sup>3</sup> PEL Respirable Fraction	5 mg/m <sup>3</sup> TWA Respirable

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Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Propylene Glycol	Not Available	10 mg/m <sup>3</sup> TWA (WEEL)	Not Available
Methylparaben	Not Available	Not Available	Not Available
Propylparaben	Not Available	Not Available	Not Available
Glycerin	10 mg/m <sup>3</sup> TWA	5 mg/m <sup>3</sup> TWA	Not Available
Sorbitol Solution	Not Available	Not Available	Not Available
Sodium Saccharin	Not Available	Not Available	Not Available
Premium Lemon Flavor	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.

Hygiene measures:

Wash hands thoroughly after use.

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

Physical state:

Liquid

Odor:

Lemon

Appearance:

White, Opaque suspension which may separate on standing

Odor threshold:

Not available

Property	Values	Remarks/Method
pH	9.0 – 11.0	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	

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Property	Values	Remarks/Method
Specific gravity	1.2000 – 1.3000	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.

**Hazardous decomposition products**

None known

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## 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
Magnesium Hydroxide Gel	8500 mg/kg Rat	Not Available	Not Available
Methocel (Hypromellose)	>10000 mg/kg Rat	Not Available	Not Available
Sodium Citrate Dihydrate	Not Available	Not Available	Not Available
Sucrose	29700 mg/kg Rat	Not Available	Not Available
Propylene Glycol	>5000 mg/kg Rat	>2000 mg/kg Rabbit	>20mg/l Rabbit
Methylparaben	2100 mg/kg Rat	No skin irritation 24 hr. Rabbit	Not Available
Propylparaben	6000 mg/kg Mouse/Rat	Not Available	Not Available
Glycerin	12600 mg/kg Rat	>10000 mg/kg Rabbit	>570 mg/l Rat
Sorbitol Solution	15900 mg/kg Rat	Not Available	Not Available
Sodium Saccharin	14200 mg/kg Rat	Not Available	Not Available
Premium Lemon Flavor	Not Available	Not Available	Not Available

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

None

### 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)
Magnesium Hydroxide Gel	Not Available	Not Available	Not Available	Not Available
Methocel (Hypromellose)	Not Available	>100 mg/L	Not Available	Not Available
Sodium Citrate Dihydrate	Not Available	Not Available	Not Available	Not Available
Sucrose	Not Available	Not Available	Not Available	Not Available
Propylene Glycol	Not Available	52930 mg/L 96 hr Pimephales Promelas	Not Available	13020 mg/L 48 hr.
Methylparaben	91 mg/L 72 hr. Pseudokirchneriella subcapitata	59.5 mg/L 89 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 hr. Danio rerio	Not Available	15.4 mg/L 72hr.
Glycerin	Not Available	58.5 ppm 96 hr Trout	Not Available	Not Available
Sorbitol Solution	Not Available	Not Available	Not Available	Not Available
Sodium Saccharin	Not Available	Not Available	Not Available	Not Available
Premium Lemon 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.



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## 14. Transport information

### Notes:

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

## 15. Regulatory information

### International inventories

### Legend

### U.S. Federal regulations;

Not applicable

Chemical name	California Listed	TSCA Listed (8b)	EINECS	Sara 311/312
Magnesium Hydroxide Gel	No	No	No	Not Applicable
Methocel (Hypromellose)	No	Listed	Listed	Not Applicable
Sodium Citrate Dihydrate	No	No	Listed	Not Applicable
Sucrose	No	Listed	Listed	Not Applicable
Propylene Glycol	No	Listed	Listed	Not Applicable
Methylparaben	No	Listed	Listed	Not Applicable
Propylparaben	No	Listed	Listed	Not Applicable
Glycerin	No	Listed	Listed	Not Applicable
Sorbitol Solution	No	No	No	Not Applicable
Sodium Saccharin	No	Listed	Listed	Not Applicable
Premium Lemon Flavor	No	No	No	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 are listed under CERCLA.**

### California Proposition 65:

This product does not contain any ingredients listed as Proposition 65 chemicals.

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## 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
Magnesium Hydroxide Gel					
Methocel (Hypromellose)	X		X		
Sodium Citrate Dihydrate	X		X		
Sucrose	X	X	X		
Propylene Glycol	X		X		
Methylparaben	X		X		
Propylparaben	X		X		
Glycerin	X	X	X	X	X
Sorbitol Solution	X		X		
Sodium Saccharin	X	X	X		
Premium Lemon Flavor					

## U.S. EPA label information:

Not applicable

## 16. Other information

Prepared by:

Pharmaceutical Associates Inc.

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Revision note:

New SDS

### 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**