

# SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078942184

N/A

# SAFETY DATA SHEET

Issuing Date No data available

Revision Date 22-Apr-2016

Revision Number 1



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## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

### Product identifier

Product Name Infants Gas Relief Drops Simethicone Oral Suspension USP

### Other means of identification

Synonyms None

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

Recommended Use OTC Medicinal liquid

Uses advised against No information available

### Details of the supplier of the safety data sheet

Supplier Name Geri-Care Pharmaceuticals

Supplier Address 1650 63rd Street  
Brooklyn  
NY  
11204  
US

Supplier Phone Number Phone:718-234-8800

Supplier Email marty@gericarepharm.com

### Emergency telephone number

Company Emergency Phone Number 718-234-8800

## 2. HAZARDS IDENTIFICATION

### Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

### GHS Label elements, including precautionary statements

#### Emergency Overview



The product contains no substances which at their given concentration, are considered to be hazardous to health.

**Appearance** Opaque white                              **Physical state** Liquid                              **Odor** Cherry

**Precautionary Statements - Prevention**  
 None

**Precautionary Statements - Response**  
 None

**Precautionary Statements - Storage**  
 None

**Precautionary Statements - Disposal**  
 None

**Hazards not otherwise classified (HNOC)**

Not applicable

**Unknown Toxicity**

11 % of the mixture consists of ingredient(s) of unknown toxicity

**Other information**

May cause slight eye irritation

**Interactions with Other Chemicals**

No information available.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

<b>Chemical name</b>	<b>CAS No</b>	<b>Weight-%</b>	<b>Trade Secret</b>
Microcrystalline cellulose	9004-34-6	1 - 5	*

\*The exact percentage (concentration) of composition has been withheld as a trade secret

**4. FIRST AID MEASURES**

**First aid measures**

**Eye contact**                              Rinse thoroughly with plenty of water, also under the eyelids. If symptoms persist, call a physician.

**Skin contact**                              Wash with soap and water.

**Inhalation**                                  Remove to fresh air.

**Ingestion**                                  Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an



unconscious person.

**Most important symptoms and effects, both acute and delayed**

**Most Important Symptoms and Effects** No information available.

**Indication of any immediate medical attention and special treatment needed**

**Notes to Physician** Treat symptomatically.

**5. FIRE-FIGHTING MEASURES**

**Suitable Extinguishing Media**

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Unsuitable extinguishing media**

CAUTION: Use of water spray when fighting fire may be inefficient.

**Specific hazards arising from the chemical**

No information available.

**Hazardous Combustion Products**

Carbon oxides.

**Explosion Data**

**Sensitivity to Mechanical Impact** No.

**Sensitivity to Static Discharge** No.

**Protective equipment and precautions for firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

**6. ACCIDENTAL RELEASE MEASURES**

**Personal precautions, protective equipment and emergency procedures**

**Personal precautions** Avoid contact with eyes.

**Environmental precautions**

**Environmental precautions** Refer to protective measures listed in Sections 7 and 8.

**Methods and material for containment and cleaning up**

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Pick up and transfer to properly labeled containers. Soak up with inert absorbent material.



## 7. HANDLING AND STORAGE

### Precautions for safe handling

**Handling** Handle in accordance with good industrial hygiene and safety practice. Avoid contact with eyes.

### Conditions for safe storage, including any incompatibilities

**Storage** Keep container tightly closed.

**Incompatible Products** None known based on information supplied.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

#### Exposure Guidelines

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Microcrystalline cellulose 9004-34-6	TWA: 10 mg/m <sup>3</sup>	TWA: 15 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable fraction (vacated) TWA: 15 mg/m <sup>3</sup> total dust (vacated) TWA: 5 mg/m <sup>3</sup> respirable fraction	TWA: 10 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable dust

*ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value OSHA PEL: Occupational Safety and Health Administration - Permissible Exposure Limits NIOSH IDLH Immediately Dangerous to Life or Health*

**Other Exposure Guidelines** Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992)

### Appropriate engineering controls

**Engineering Measures** Showers  
Eyewash stations  
Ventilation systems

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

**Eye/face protection** No special protective equipment required.

**Skin and body protection** No special protective equipment required.

**Respiratory protection** No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

**Hygiene Measures** Handle in accordance with good industrial hygiene and safety practice.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Physical and Chemical Properties

**Physical state** Liquid



<b>Appearance</b>	Opaque white	<b>Odor</b>	Cherry
<b>Color</b>	No information available	<b>Odor Threshold</b>	No information available
<b>Property</b>	<b>Values</b>	<b>Remarks</b>	<b>Method</b>
pH	5	None known	
Melting / freezing point	No data available	None known	
Boiling point / boiling range	No data available	None known	
Flash Point	No data available	None known	
Evaporation Rate	No data available	None known	
Flammability (solid, gas)	No data available	None known	
Flammability Limit in Air			
Upper flammability limit	No data available		
Lower flammability limit	No data available		
Vapor pressure	No data available	None known	
Vapor density	No data available	None known	
Specific Gravity	1.05	None known	
Water Solubility	Dispersible	None known	
Solubility in other solvents	No data available	None known	
Partition coefficient: n-octanol/water	No data available	None known	
Autoignition temperature	No data available	None known	
Decomposition temperature	No data available	None known	
Kinematic viscosity	No data available	None known	
Dynamic viscosity	No data available	None known	
Explosive properties	No data available		
Oxidizing properties	No data available		

**Other Information**

Softening Point	No data available
VOC Content (%)	No data available
Particle Size	No data available
Particle Size Distribution	

**10. STABILITY AND REACTIVITY**

**Reactivity**

No data available.

**Chemical stability**

Stable under recommended storage conditions.

**Possibility of Hazardous Reactions**

None under normal processing.

**Hazardous Polymerization**

Hazardous polymerization does not occur.

**Conditions to avoid**

None known based on information supplied.

**Incompatible materials**

None known based on information supplied.

**Hazardous Decomposition Products**

Carbon oxides.

**11. TOXICOLOGICAL INFORMATION**



**Information on likely routes of exposure**

**Product Information**

**Inhalation** Specific test data for the substance or mixture is not available.  
**Eye contact** Specific test data for the substance or mixture is not available.  
**Skin contact** Specific test data for the substance or mixture is not available.  
**Ingestion** Specific test data for the substance or mixture is not available.

**Component Information**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Microcrystalline cellulose 9004-34-6	> 5 g/kg ( Rat )	> 2 g/kg ( Rabbit )	> 5800 mg/m <sup>3</sup> ( Rat ) 4 h

**Information on toxicological effects**

**Symptoms** No information available.

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**Sensitization** No information available.  
**Mutagenic Effects** No information available.  
**Carcinogenicity** The table below indicates whether each agency has listed any ingredient as a carcinogen.  
**Reproductive toxicity** No information available.  
**STOT - single exposure** No information available.  
**STOT - repeated exposure** No information available.  
**Chronic Toxicity** No known effect based on information supplied.  
**Target Organ Effects** Eyes. Respiratory system. Skin.  
**Aspiration Hazard** No information available.

**Numerical measures of toxicity Product Information**

The following values are calculated based on chapter 3.1 of the GHS document  
 Not applicable



## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

The environmental impact of this product has not been fully investigated.

### Persistence and Degradability

No information available.

### Bioaccumulation

### Other adverse effects

No information available.

## 13. DISPOSAL CONSIDERATIONS

### Waste treatment methods

#### **Disposal methods**

This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

#### **Contaminated Packaging**

Dispose of contents/containers in accordance with local regulations.

## 14. TRANSPORT INFORMATION

<u>DOT</u> Proper Shipping Name Hazard Class	NOT REGULATED NON REGULATED N/A
<u>TDG</u>	Not regulated
<u>MEX</u>	Not regulated
<u>ICAO</u>	Not regulated
<u>IATA</u> Proper Shipping Name Hazard Class	Not regulated NON REGULATED N/A
<u>IMDG/IMO</u> Hazard Class	Not regulated N/A
<u>RID</u>	Not regulated
<u>ADR</u>	Not regulated





ADN Not regulated

**15. REGULATORY INFORMATION**

**International Inventories**

TSCA Complies  
DSL All components are listed either on the DSL or NDSL.

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory  
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

**US Federal Regulations**

**SARA 313**

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 40 of the Code of Federal Regulations, Part 372

**SARA 311/312 Hazard Categories**

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

**CWA (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**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

**US State Regulations**

**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

**U.S. State Right-to-Know Regulations**

Chemical name	New Jersey	Massachusetts	Pennsylvania	Rhode Island	Illinois
Microcrystalline cellulose 9004-34-6	X	X	X	-	X

**International Regulations**

**Mexico**

**National occupational exposure limits**

Chemical name	Carcinogen Status	Exposure Limits
Microcrystalline cellulose		Mexico: TWA 10 mg/m <sup>3</sup> Mexico: STEL 20 mg/m <sup>3</sup>

Mexico - Occupational Exposure Limits - Carcinogens

**Canada**

**WHMIS Hazard Class**



Not determined

**16. OTHER INFORMATION**

NFPA	Health Hazards 0	Flammability 0	Instability 0	Physical and Chemical Hazards -
HMIS	Health Hazards 0	Flammability 0	Physical Hazard 0	Personal Protection X

Prepared By Product Stewardship  
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Revision Date 22-Apr-2016

Revision Note No information available

**Disclaimer**

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**End of Safety Data Sheet**

