



MATERIAL SAFETY DATA SHEET

Revision date: 19-Dec-2007

Version: 1.0

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

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Material Name: SOLUGASTRIL Tablets

Trade Name:	SOLUGASTRIL
Chemical Family:	Not determined
Intended Use:	Pharmaceutical product for the treatment of heartburn, gastrointestinal disorders

2. HAZARDS IDENTIFICATION

Appearance:	White tablets
Statement of Hazard:	Non-hazardous in accordance with international standards for workplace safety.
Additional Hazard Information:	
Short Term:	Dust may cause irritation if tablets are crushed or broken. Acute toxicity following ingestion is not expected.
Known Clinical Effects:	Aluminum hydroxide may cause nausea, vomiting, and constipation. Large doses can cause intestinal obstruction.
EU Indication of danger:	Not classified

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 for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

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Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Calcium carbonate	1317-65-3	215-279-6	Not Listed	600***
Aluminum hydroxide	21645-51-2	244-492-7	Not Listed	12.5***
Polyethylene glycol	25322-68-3	Not listed	Not Listed	*
Silicon dioxide, NF	7631-86-9	231-545-4 EEC No. 418-260-2	Not Listed	*
Starch	9005-25-8	232-679-6	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Sodium cyclamate	139-05-9	205-348-9	Not Listed	*
Mannitol	69-65-8	200-711-8	Not Listed	*

Additional Information:

*** per tablet/capsule/lozenge/suppository
* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

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Measures for Environmental Protections:

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

Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling:

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8).

Storage Conditions:

Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Calcium carbonate

Australia TWA	= 10 mg/m ³ TWA	
Belgium OEL - TWA	= 10 mg/m ³ TWA	
Bulgaria OEL - TWA	= 1.0 f/cm ³ TWA	containing <2% uncombined silicon dioxide
	= 10.0 mg/m ³ TWA	
Czech Republic OEL - TWA	= 10.0 mg/m ³ TWA	
Estonia OEL - TWA	= 10 mg/m ³ TWA	
	= 5 mg/m ³ TWA	
France OEL - TWA	= 10 mg/m ³ VME	
Greece OEL - TWA	= 10 mg/m ³ TWA	
	= 5 mg/m ³ TWA	
Hungary OEL - TWA	= 10 mg/m ³ TWA	
Ireland OEL - TWAs	= 10 mg/m ³ TWA	
	= 4 mg/m ³ TWA	
Netherlands OEL - TWA	= 10 mg/m ³ MAC	
OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA	total
	= 5 mg/m ³ TWA	
Portugal OEL - TWA	= 10 mg/m ³ TWA	
Slovakia OEL - TWA	= 10 mg/m ³ TWA	

Aluminum hydroxide

ACGIH OELs - Notice of Intended Changes	Listed	
Bulgaria OEL - TWA	= 1.5 mg/m ³ TWA	
	= 10.0 mg/m ³ TWA	
Czech Republic OEL - TWA	= 10.0 mg/m ³ TWA	except for gamma Al ₂ O ₃
Latvia OEL - TWA	= 6 mg/m ³ TWA	
Lithuania OEL - TWA	= 6 mg/m ³ IPRV	
Poland OEL - TWA	= 1.2 mg/m ³ NDS	
	= 2.5 mg/m ³ NDS	
Slovakia OEL - TWA	= 1.5 mg/m ³ TWA	

Polyethylene glycol

Austria OEL - MAKs	= 1000 mg/m ³ MAK
Germany - TRGS 900 - TWAs	= 1000 mg/m ³ TWA
Netherlands OEL - TWA	= 1000 mg/m ³ MAC
Slovakia OEL - TWA	= 1000 mg/m ³ TWA

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Slovenia OEL - TWA	= 1000 mg/m ³ TWA
Silicon dioxide, NF	
Australia TWA	= 2 mg/m ³ TWA
Austria OEL - MAKs	= 4 mg/m ³ MAK
Czech Republic OEL - TWA	= 0.1 mg/m ³ TWA
	= 4.0 mg/m ³ TWA
Estonia OEL - TWA	= 2 mg/m ³ TWA
Germany - TRGS 900 - TWAs	= 4 mg/m ³ TWA
Ireland OEL - TWAs	= 2.4 mg/m ³ TWA
	= 6 mg/m ³ TWA
Latvia OEL - TWA	= 1 mg/m ³ TWA containing more than 70% SiO ₂ (quartz)
	= 2 mg/m ³ TWA containing 10-70% SiO ₂ (granite, mica)
	= 4 mg/m ³ TWA containing 2-10% SiO ₂ (copper sulfate ores)
OSHA - Final PELs - Table Z-3 Mineral D:	(80)/(% SiO ₂) mg/m ³ TWA
	= 20 mppcf TWA
Slovakia OEL - TWA	= 4.0 mg/m ³ TWA
Slovenia OEL - TWA	= 4 mg/m ³ TWA
Starch	
ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA
Australia TWA	= 10 mg/m ³ TWA
Belgium OEL - TWA	= 10 mg/m ³ TWA
Bulgaria OEL - TWA	= 10.0 mg/m ³ TWA
Czech Republic OEL - TWA	= 4.0 mg/m ³ TWA
Greece OEL - TWA	= 10 mg/m ³ TWA
	= 5 mg/m ³ TWA
Ireland OEL - TWAs	= 10 mg/m ³ TWA
	= 4 mg/m ³ TWA
OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA total
	= 5 mg/m ³ TWA
Portugal OEL - TWA	= 10 mg/m ³ TWA
Spain OEL - TWA	= 10 mg/m ³ VLA-ED

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection:	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Tablets	Color:	White
Molecular Formula:	Mixture	Molecular Weight:	Mixture

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10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Mannitol

Rat Oral LD 50 13500 mg/kg
Mouse Oral LD 50 22 g/kg

Sodium cyclamate

Rat Oral LD50 1280 mg/kg

Starch

Mouse IP LD50 6600 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Polyethylene glycol

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Sodium cyclamate

IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

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14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

Calcium carbonate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	215-279-6

Sodium cyclamate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	205-348-9

Aluminum hydroxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	244-492-7

Polyethylene glycol

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Mannitol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-711-8

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Silicon dioxide, NF

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-545-4 EEC No. 418-260-2

Starch

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6

16. OTHER INFORMATION

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet