



MATERIAL SAFETY DATA SHEET

Revision date: 20-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 Gel

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

2. HAZARDS IDENTIFICATION

Appearance:	Gel
Statement of Hazard:	Non-hazardous in accordance with international standards for workplace safety.
Additional Hazard Information:	
Short Term:	May cause eye irritation (based on components) . May cause allergic reactions in susceptible individuals. 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
Australian Hazard Classification (NOHSC):	Non-Hazardous Substance. Non-Dangerous Goods.
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	600mg/10g
Aluminum hydroxide	21645-51-2	244-492-7	Not Listed	435mg/10g
Silicon dioxide, NF	7631-86-9	231-545-4 EEC No. 418-260-2	Not Listed	*
Bergamot oil	8007-75-8	Not listed	Not Listed	*
Ethanol	64-17-5	200-578-6	F;R11	<1

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Vanillin	121-33-5	204-465-2	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	*
Hydroxyethyl cellulose	9004-62-0	Not listed	Not Listed	*
Methylparaben	99-76-3	202-785-7	Not Listed	*
Potassium sorbate	24634-61-5	246-376-1	Not Listed	*
Sorbitol	6706-59-8	Not listed	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

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: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

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

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- Measures for Cleaning / Collecting:** Contain the source of the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.
- 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:** Restrict access to work area. Avoid open handling. Minimize generating airborne mists and vapors. Use process containment, local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided.
- 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	

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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

Ethanol

ACGIH Threshold Limit Value (TWA)	= 1000 ppm TWA
Australia TWA	= 1000 ppm TWA
	= 1880 mg/m ³ TWA
Austria OEL - MAKs	= 1000 ppm MAK
	= 1900 mg/m ³ MAK
Belgium OEL - TWA	= 1000 ppm TWA
	= 1907 mg/m ³ TWA
Bulgaria OEL - TWA	= 1000.0 mg/m ³ TWA
Czech Republic OEL - TWA	= 1000 mg/m ³ TWA
Denmark OEL - TWA	= 1000 ppm TWA
	= 1900 mg/m ³ TWA
Estonia OEL - TWA	= 1000 mg/m ³ TWA
	= 500 ppm TWA
Finland OEL - TWA	= 1000 ppm TWA
	= 1900 mg/m ³ TWA
France OEL - TWA	= 1000 ppm VME
	= 1900 mg/m ³ VME
Germany - TRGS 900 - TWAs	= 500 ppm TWA
	= 960 mg/m ³ TWA
Greece OEL - TWA	= 1000 ppm TWA
	= 1900 mg/m ³ TWA
Hungary OEL - TWA	= 1900 mg/m ³ TWA
Ireland OEL - TWAs	= 1000 ppm TWA
	= 1900 mg/m ³ TWA
Latvia OEL - TWA	= 1000 mg/m ³ TWA
Lithuania OEL - TWA	= 1000 mg/m ³ IPRV
	= 500 ppm IPRV
Netherlands OEL - TWA	= 1000 mg/m ³ MAC
	= 500 ppm MAC
OSHA - Final PELs - TWAs:	= 1000 ppm TWA
	= 1900 mg/m ³ TWA
Poland OEL - TWA	= 1900 mg/m ³ NDS
Portugal OEL - TWA	= 1000 ppm TWA
Romania OEL - TWA	= 1000 ppm TWA
	= 1900 mg/m ³ TWA

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Slovakia OEL - TWA	= 500 ppm TWA = 960 mg/m ³ TWA
Slovenia OEL - TWA	= 1000 ppm TWA = 1900 mg/m ³ TWA
Spain OEL - TWA	= 1000 ppm VLA-ED = 1910 mg/m ³ VLA-ED
Sweden OEL - TWAs	= 1000 mg/m ³ LLV = 500 ppm LLV

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:	Gel	Color:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

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)

Ethanol

Mouse	Oral	LD50	3,450 g/m ³
Rat	Oral	LD50	7,060 mg/kg
Mouse	Inhalation	LC50 4h	39 g/m ³
Rat	Inhalation	LC50 10h	20,000 ppm

Vanillin

Rat	Oral	LD 50	1580 mg/kg
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Potassium sorbate

Rat Oral LD 50 4.34 gm/kg

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

Ethanol

Eye Irritation Rabbit Severe

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

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Ethanol

Fingerling Trout	NPDES	LC50	24 Hours	11,200 mg/L
Rainbow Trout	NPDES	LC50	96 Hours	12,900 mg/L
Fathead minnow	NPDES	LC50	96 Hours	14,200 mg/L

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.

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.

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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

Aluminum hydroxide

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

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

Vanillin

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	204-465-2

Water, purified

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	231-791-2

Hydroxyethyl cellulose

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

Methylparaben

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-785-7

Bergamot oil

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5

Potassium sorbate

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Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	246-376-1

Ethanol

California Proposition 65	developmental toxicity, initial date 10/1/87 (when in alcoholic beverages)
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-578-6

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R11 - Highly flammable.

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

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

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet