



MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

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

Pfizer Inc
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Lithium Carbonate Tablets

Trade Name: Lithane
Chemical Family: Mixture
Intended Use: Pharmaceutical product used for manic episodes

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Lithium Carbonate	554-13-2	209-062-5	150/300 mg ***
Sodium Lauryl Sulfate	151-21-3	205-788-1	*
Titanium dioxide	13463-67-7	236-675-5	*
Silicon dioxide, NF	7631-86-9	231-545-4	*

Ingredient	CAS Number	EU EINECS List	%
Gelatin	9000-70-8	232-554-6	*
FD&C Green No. 3	2353-45-9	219-091-5	*
D & C yellow No. 10	8004-92-0	Not listed	*
FD&C yellow No.6 aluminum lake	15790-07-5	239-888-1	*

Additional Information:

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

3. HAZARDS IDENTIFICATION

Appearance: Light-green round tablet
Signal Word: DANGER

Statement of Hazard: Harmful if swallowed.
May damage the unborn child.

Additional Hazard Information:

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on kidneys.
Known Clinical Effects: Clinical use of this drug has caused nausea, diarrhea, vertigo, muscle weakness frequent urination, skin effects clumsy motion of limbs/trunk (ataxia), ringing of the ears, blurred vision, drowsiness, toxic psychosis seizure, electrolyte imbalance, coma.

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EU Indication of danger: Harmful
Toxic to Reproduction: Category 2

EU Hazard Symbols:



EU Risk Phrases:
R22 - Harmful if swallowed.
R61 - May cause harm to the unborn child.

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.

4. FIRST AID MEASURES

Eye Contact: Flush with water for 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get 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. If not breathing, give artificial respiration. Get medical attention.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Carbon monoxide and carbon dioxide

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.

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.

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7. HANDLING AND STORAGE

General Handling: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Avoid generating airborne dust. Wash thoroughly after handling.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Titanium dioxide

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Silicon dioxide, NF

OSHA - Final PELs - Table Z-3 Mineral D: (80)/(% SiO₂) mg/m³ TWA
= 20 mppcf TWA
Australia TWA = 2 mg/m³ TWA

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Lithium Carbonate

Pfizer Occupational Exposure Band (OEB): OEB3 (control exposure to the range of >10ug/m³ to < 100ug/m³)

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.
Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.
Respiratory protection: None required under normal conditions of use. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Tablet	Color:	Light green
Molecular Formula:	Mixture	Molecular Weight:	Mixture

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10. STABILITY AND REACTIVITY

Stability: Stable
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)

Lithium Carbonate

Rat Oral LD50 525
Mouse Oral LD50 531
Rat Intravenous LD50 241

Silicon dioxide, NF

Rat Oral LD50 10 g/kg

Sodium Lauryl Sulfate

Rat Oral LD 50 1288 mg/kg
Rat Intraperitoneal LD 50 210 mg/kg

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD 50 50 mg/kg

D & C yellow No. 10

Rat Oral LD50 2000 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Lithium Carbonate

60 Day(s) Rat Intraperitoneal 10 mg/kg/day LOEL Kidney

Sodium Lauryl Sulfate

3 Day(s) Rat Oral 75 mg/kg LOAEL Liver, Blood

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Lithium Carbonate

Embryo / Fetal Development Mouse Oral 300 mg/kg/day LOEL Teratogenic
Embryo / Fetal Development Rat Oral 50 mg/kg/day NOEL Fetotoxicity, Teratogenic
Embryo / Fetal Development Mouse Oral 3.2 mg/kg/day NOEL Teratogenic, Fetotoxicity

Carcinogen Status: See below

Silicon dioxide, NF

IARC: Group 3

Titanium dioxide

IARC: Group 2B

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OSHA: Present

FD&C Green No. 3
IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Harmful
Toxic to Reproduction: Category 2

EU Risk Phrases:
R22 - Harmful if swallowed.
R61 - May cause harm to the unborn child.

EU Safety Phrases:
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
DANGER
Harmful if swallowed.
May damage the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A

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Lithium Carbonate

CERCLA/SARA 313 Emission reporting	= 1.0 % de minimis concentration
California Proposition 65	developmental toxicity, initial date 1/1/91
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2
EU EINECS List	Schedule 4 209-062-5

Gelatin

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-554-6

Sodium Lauryl Sulfate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	205-788-1

Titanium dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	236-675-5

FD&C Green No. 3

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	219-091-5

Silicon dioxide, NF

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-545-4

D & C yellow No. 10

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

FD&C yellow No.6 aluminum lake

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	239-888-1

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations.

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Prepared by:

Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet