



# MATERIAL SAFETY DATA SHEET

Revision date: 25-Jun-2008

Version: 1.2

Page 1 of 9

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

**Pfizer Inc**  
Pfizer Pharmaceuticals Group  
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**Pfizer Ltd**  
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United Kingdom  
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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: Spironolactone Tablets

<b>Trade Name:</b>	ALDACTONE; ALDACTONE-A; PRACTON
<b>Chemical Family:</b>	Mixture
<b>Intended Use:</b>	Pharmaceutical product for the treatment of high blood pressure (hypertension).

## 2. HAZARDS IDENTIFICATION

**Appearance:** Yellow, Orange, Peach Tablet  
**Signal Word:** WARNING

**Statement of Hazard:** Suspected of causing cancer.  
May cause damage to: blood and blood-forming organs through prolonged or repeated exposure.

**Additional Hazard Information:**  
**Short Term:** May be absorbed through the skin and cause systemic effects. Antihypertensive drug: has blood pressure-lowering properties

**Known Clinical Effects:** Adverse effects seen in clinical use include gastrointestinal discomfort, dizziness, and headache. Hypersensitivity reactions may also occur in susceptible individuals. Effects on blood and blood-forming organs have also occurred.

**EU Indication of danger:** Toxic to Reproduction: Category 2  
Carcinogenic: Category 3  
Harmful

**EU Hazard Symbols:**



**EU Risk Phrases:** R40 - Limited evidence of a carcinogenic effect  
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.  
R60 - May impair fertility.

# MATERIAL SAFETY DATA SHEET

Material Name: Spironolactone Tablets  
Revision date: 25-Jun-2008

Page 2 of 9  
Version: 1.2

## 2. HAZARDS IDENTIFICATION

**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

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Spironolactone	52-01-7	200-133-6	Repr.Cat.2;R60 Carc.Cat3;R40 Xn;R48/22	10-20%
Maize starch	9005-25-8	232-679-6	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Polyethylene glycol	25322-68-3	Not listed	Not Listed	*
Calcium sulfate, dihydrate	10101-41-4	Not listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Povidone	9003-39-8	Not listed	Not Listed	*
Peppermint flavor	8006-90-4	Not listed	Not Listed	*
Hypromellose	9004-65-3	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:** Emits oxides of sulfur under combustion.

## MATERIAL SAFETY DATA SHEET

Material Name: Spironolactone Tablets  
Revision date: 25-Jun-2008

Page 3 of 9  
Version: 1.2

**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.

### 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 in a cool, dry, well-ventilated area. Protect from heat and light.

## MATERIAL SAFETY DATA SHEET

Material Name: Spironolactone Tablets  
Revision date: 25-Jun-2008

Page 4 of 9  
Version: 1.2

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Spironolactone

Manufacturer OEL: 90ug/m<sup>3</sup>, Skin

#### Maize starch

ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA  
Belgium OEL - TWA Listed  
Bulgaria OEL - TWA Listed  
Czech Republic OEL - TWA Listed  
Greece OEL - TWA Listed  
Ireland OEL - TWAs = 10 mg/m<sup>3</sup> TWA  
= 4 mg/m<sup>3</sup> TWA  
OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
Portugal OEL - TWA Listed  
Spain OEL - TWA Listed

#### Magnesium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA except stearates of toxic metals  
Australia TWA = 10 mg/m<sup>3</sup> TWA  
Belgium OEL - TWA Listed  
Ireland OEL - TWAs = 10 mg/m<sup>3</sup> TWA except lead stearate  
Lithuania OEL - TWA Listed  
Portugal OEL - TWA Listed  
Spain OEL - TWA Listed  
Sweden OEL - TWAs = 5 mg/m<sup>3</sup> LLV

#### Polyethylene glycol

Austria OEL - MAKs Listed  
Germany - TRGS 900 - TWAs = 1000 mg/m<sup>3</sup> TWA  
Germany (DFG) - MAK = 1000 mg/m<sup>3</sup> MAK average molecular weight 200-600  
Netherlands OEL - TWA Listed  
Slovenia OEL - TWA Listed

#### Calcium sulfate, dihydrate

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup> TWA  
Australia TWA 10 mg/m<sup>3</sup>  
Austria OEL - MAKs Listed  
Belgium OEL - TWA Listed  
Bulgaria OEL - TWA Listed  
France OEL - TWA Listed  
Germany - TRGS 900 - TWAs 6 mg/m<sup>3</sup>  
Germany (DFG) - MAK 1.5 mg/m<sup>3</sup> MAK  
4 mg/m<sup>3</sup> MAK  
Greece OEL - TWA Listed  
Hungary OEL - TWA Listed  
Ireland OEL - TWAs Listed  
Netherlands OEL - TWA Listed  
OSHA - Final PELs - TWAs: 15 mg/m<sup>3</sup> total  
5 mg/m<sup>3</sup>  
Poland OEL - TWA Listed

## MATERIAL SAFETY DATA SHEET

Material Name: Spironolactone Tablets  
Revision date: 25-Jun-2008

Page 5 of 9  
Version: 1.2

Portugal OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed

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

**Analytical Method:** Analytical method available for spironolactone. Contact Pfizer Inc for further information.  
**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:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**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:

<b>Physical State:</b>	Tablet	<b>Color:</b>	Yellow; Orange; Peach
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	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.

## MATERIAL SAFETY DATA SHEET

Material Name: Spironolactone Tablets  
Revision date: 25-Jun-2008

Page 6 of 9  
Version: 1.2

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

#### **Spironolactone**

Rat Oral LD 50 4121 mg/kg  
Mouse Oral LD 50 >1000 mg/kg  
Rabbit Oral LD 50 >1000 mg/kg  
Rat Intraperitoneal LD 50 786 mg/kg

#### **Povidone**

Rat Oral LD50 100 g/kg

#### **Magnesium stearate**

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

#### **Hypromellose**

Rat Oral LD50 > 10,000 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.

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

#### **Spironolactone**

Skin Sensitization - GPMT Guinea Pig No effect

#### **Polyethylene glycol**

Eye Irritation Rabbit Mild  
Skin Irritation Rabbit Mild

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

#### **Spironolactone**

13 Week(s) Rat Oral 50 mg/kg LOAEL Blood  
78 Week(s) Rat Oral 50 mg/kg/day LOAEL Liver, Male reproductive system

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

#### **Spironolactone**

Reproductive & Fertility Rat Oral 15 mg/kg/day NOAEL Fetotoxicity  
Reproductive & Fertility Rat Intraperitoneal 100 mg/kg/day LOAEL Fertility  
Embryo / Fetal Development Mouse Intraperitoneal 100 mg/kg/day LOAEL Maternal Toxicity  
Embryo / Fetal Development Rat Oral 50 mg/kg/day LOAEL Fetotoxicity  
Embryo / Fetal Development Rabbit Oral 20 mg/kg/day LOAEL Fetotoxicity

### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

## MATERIAL SAFETY DATA SHEET

Material Name: Spironolactone Tablets  
Revision date: 25-Jun-2008

Page 7 of 9  
Version: 1.2

### Spironolactone

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative  
Mammalian Cell Mutagenicity Negative without activation

### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

### Spironolactone

104 Week(s) Rat Oral 10 mg/kg/day LOAEL Benign tumors  
52 Week(s) Non-human Primate Oral 20 mg/kg/day LOAEL Reproductive System

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

### Spironolactone

**IARC:** Group 3 (Not Classifiable)

### Povidone

**IARC:** Group 3 (Not Classifiable)

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Releases to the environment should be avoided. Environmental properties have not been thoroughly 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. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

## 14. TRANSPORT INFORMATION

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

# MATERIAL SAFETY DATA SHEET

Material Name: Spironolactone Tablets  
Revision date: 25-Jun-2008

Page 8 of 9  
Version: 1.2

## 15. REGULATORY INFORMATION

**EU Symbol:** T  
**EU Indication of danger:** Toxic to Reproduction: Category 2  
Carcinogenic: Category 3  
Harmful

**EU Risk Phrases:**  
R40 - Limited evidence of a carcinogenic effect  
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.  
R60 - May impair fertility.

**EU Safety Phrases:**  
S22 - Do not breathe dust.  
S24 - Avoid contact with skin.  
S36/37 - Wear suitable protective clothing and gloves.  
S53 - Avoid exposure - obtain special instructions before use.

**OSHA Label:**  
WARNING  
Suspected of causing cancer.  
May cause damage to: blood and blood-forming organs through prolonged or repeated exposure.

### Canada - WHMIS: Classifications

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



### Spironolactone

California Proposition 65	carcinogen, initial date 5/1/97
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	200-133-6

### Maize 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

### Povidone

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



## MATERIAL SAFETY DATA SHEET

Material Name: Spironolactone Tablets  
Revision date: 25-Jun-2008

Page 9 of 9  
Version: 1.2

### Peppermint flavor

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

### Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

### Hypromellose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

### Polyethylene glycol

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

### Calcium sulfate, dihydrate

Australia (AICS):	Listed
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## 16. OTHER INFORMATION

### Text of R phrases mentioned in Section 3

R40 - Limited evidence of a carcinogenic effect

R60 - May impair fertility.

R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

**Data Sources:** Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 9 - Physical and Chemical Properties. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

**Prepared by:** Corporate Occupational Toxicology & Hazard Assessment

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**