



MATERIAL SAFETY DATA SHEET

Revision date: 03-Apr-2012

Version: 1.3

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Material Name: Spironolactone Tablets

| | |
|------------------|---|
| Trade Name: | ALDACTONE; ALDACTONE-A; PRACTON |
| Chemical Family: | Mixture |
| Intended Use: | 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.

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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 | EU Classification | % |
|----------------------------|------------|-----------------------|--|--------|
| Spironolactone | 52-01-7 | 200-133-6 | Repr.Cat.3;R62 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 | EU Classification | % |
|-------------------------------|------------|-----------------------|-------------------|---|
| Povidone | 9003-39-8 | Not Listed | Not Listed | * |
| Peppermint flavor | 8006-90-4 | Not Listed | Not Listed | * |
| Hydroxypropyl methylcellulose | 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.

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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). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Spironolactone

Pfizer OEL TWA-8 Hr: 90 µg/m³, Skin

Maize starch

| | |
|-----------------------------------|------------------------|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m ³ |
| Australia TWA | 10 mg/m ³ |
| Belgium OEL - TWA | 10 mg/m ³ |
| Bulgaria OEL - TWA | 10.0 mg/m ³ |
| Czech Republic OEL - TWA | 4.0 mg/m ³ |
| Greece OEL - TWA | 10 mg/m ³ |
| | 5 mg/m ³ |
| Ireland OEL - TWAs | 10 mg/m ³ |
| | 4 mg/m ³ |
| OSHA - Final PELs - TWAs: | 15 mg/m ³ |
| Portugal OEL - TWA | 10 mg/m ³ |
| Slovakia OEL - TWA | 4 mg/m ³ |
| Spain OEL - TWA | 10 mg/m ³ |

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Magnesium stearate

| | |
|-----------------------------------|----------------------|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m ³ |
| Lithuania OEL - TWA | 5 mg/m ³ |
| Sweden OEL - TWAs | 5 mg/m ³ |

Polyethylene glycol

| | |
|---------------------------|---|
| Austria OEL - MAKs | 1000 mg/m ³ |
| Germany - TRGS 900 - TWAs | 1000 mg/m ³ |
| Germany (DFG) - MAK | 1000 mg/m ³ inhalable fraction |
| Slovakia OEL - TWA | 1000 mg/m ³ |
| Slovenia OEL - TWA | 1000 mg/m ³ |

Calcium sulfate, dihydrate

| | |
|-----------------------------------|---|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m ³ |
| Germany (DFG) - MAK | 1.5 mg/m ³ respirable fraction 4 mg/m ³ inhalable fraction |
| Ireland OEL - TWAs | 10 mg/m ³ |
| Portugal OEL - TWA | 4 mg/m ³ 10 mg/m ³ |

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.

Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community environmental legislation.

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

Physical State:

Tablet

Color:

Yellow; Orange; Peach

Molecular Formula:

Mixture

Molecular Weight:

Mixture

10. STABILITY AND REACTIVITY

Chemical Stability:

Stable under normal conditions of use.

Conditions to Avoid:

None known

Incompatible Materials:

As a precautionary measure, keep away from strong oxidizers

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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)

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/m³

Hydroxypropyl methylcellulose

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)

Spironolactone

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

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11. TOXICOLOGICAL INFORMATION

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

Waste Treatment Methods:

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

The following refers to all modes of transportation unless specified below.

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

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.

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15. REGULATORY INFORMATION

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) | Present |
| 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) | Present |
| Australia (AICS): | Present |

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 |

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15. REGULATORY INFORMATION

Hydroxypropyl methylcellulose

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

Polyethylene glycol

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

Calcium sulfate, dihydrate

| | |
|-------------------|---------|
| Australia (AICS): | Present |
|-------------------|---------|

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 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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