



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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

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

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

Material Name: Spironolactone and Hydroflumethiazide Tablets

Trade Name: Aldactide(R)
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antihypertensive, diuretic.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Spironolactone	52-01-7	200-133-6	25 / 50 mg ***
Hydroflumethiazide	135-09-1	205-173-8	25 / 50 mg ***
Titanium dioxide	13463-67-7	236-675-5	*
Magnesium stearate	557-04-0	209-150-3	*
Maize starch	9005-25-8	232-679-6	*
Calcium sulfate	7778-18-9	231-900-3	*
Iron oxide	1309-37-1	215-168-2	*

Ingredient	CAS Number	EU EINECS List	%
Povidone	9003-39-8	Not listed	*
Hypromellose	9004-65-3	Not listed	*
Peppermint flavor	8006-90-4	Not listed	*
Macrogol 400	Not assigned	Not listed	*

Additional Information: *** per tablet/capsule/lozenge/suppository
* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Tablets: buff , film-coated
Signal Word: WARNING

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Statement of Hazard: Antihypertensive drug: has blood pressure-lowering properties
Suspected of damaging fertility.
Suspected of causing cancer.
May cause damage to: blood and blood forming organs through prolonged or repeated exposure.

Additional Hazard Information:
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on blood, kidneys, reproductive system.

Known Clinical Effects: Signs and symptoms might include nausea, vomiting, cramps, dizziness, headache, vertigo, low blood pressure on standing, rash, urticaria, photosensitivity, electrolyte imbalance, muscle spasm, weakness, and restlessness. Hypersensitivity reactions may also occur in susceptible individuals. Effects on blood and blood-forming organs have also occurred.

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

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.

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: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Wash 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 and keep patient at rest. Seek medical attention immediately.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides, and other fluorine- and sulfur-containing compounds.

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

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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: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Avoid generating airborne dust.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Spironolactone

Pfizer OEL TWA-8 Hr: 0.09 mg/m³, Skin

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

Magnesium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals

Australia TWA = 10 mg/m³ TWA

Maize starch

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total

= 5 mg/m³ TWA

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA

Australia TWA = 10 mg/m³ TWA

Calcium sulfate

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total

= 5 mg/m³ TWA

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA

Australia TWA = 10 mg/m³ TWA

Iron oxide

OSHA - Final PELs - TWAs: = 10 mg/m³ TWA

ACGIH Threshold Limit Value (TWA) = 5 mg/m³ TWA

Australia TWA = 5 mg/m³ TWA

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

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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.

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:** Not required for the normal use of this product. 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:	Film-coated tablets	Color:	Buff-colored
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)

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

Titanium dioxide

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

Hydroflumethiazide

Mouse Oral LD 50 > 10,000
Mouse Intraperitoneal LD 50 6280

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Hypromellose

Rat Oral LD50 > 10,000 mg/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m³

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

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

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: See below

Spironolactone

IARC: Group 3

Povidone

IARC: Group 3

Iron oxide

IARC: Group 3

Titanium dioxide

IARC: Group 2B

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OSHA: Present

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly 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
Carcinogenic: Category 3

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
Antihypertensive drug: has blood pressure-lowering properties
Suspected of damaging fertility.
Suspected of causing cancer.
May cause damage to: blood and blood forming organs through prolonged or repeated exposure.

Canada - WHMIS: Classifications

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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 List	200-133-6

Povidone

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

Hypromellose

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

Hydroflumethiazide

Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS List	205-173-8

Titanium dioxide

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

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 List	209-150-3

Maize starch

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-679-6

Calcium sulfate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-900-3

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Iron oxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	215-168-2

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. 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.

End of Safety Data Sheet