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

Product Identifier

Material Name: Spironolactone and Hydrochlorothiazide Tablets

Trade Name: Aldactazide; Aldactone HCT; Aldazida; Aldactazida

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antihypertensive, diuretic

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Reproductive Toxicity: Category 1B
Carcinogenicity: Category 2

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

EU Risk Phrases:
R40 - Limited evidence of a carcinogenic effect
R61 - May cause harm to the unborn child.

Label Elements

Signal Word: Danger
Hazard Statements: H360D - May damage the unborn child
H351 - Suspected of causing cancer

Precautionary Statements: P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations
### 3. COMPOSITION / INFORMATION ON INGREDIENTS

#### Hazardous

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iron oxide</td>
<td>1309-37-1</td>
<td>215-168-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydrochlorothiazide</td>
<td>58-93-5</td>
<td>200-403-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>&gt;1</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Calcium sulfate, dihydrate</td>
<td>10101-41-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Spironolactone</td>
<td>52-01-7</td>
<td>200-133-6</td>
<td>Repr.Cat.2,R61; Carc.Cat3;R40; Xn,R48/22</td>
<td>Carc.2 (H351); STOT RE.2 (H373); Repr.1B (H360D)</td>
<td>&lt;10</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

#### Additional Information:

- *** per tablet/capsule/lozenge/suppository
- * Proprietary
- Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
- In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

**Description of First Aid Measures**

SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE
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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Toxic or corrosive gases including oxides of carbon and oxides of sulfur

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

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.

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

Precautions for Safe Handling
SAFETY DATA SHEET

Material Name: Spironolactone and Hydrochlorothiazide

Tables
Revision date: 04-Mar-2015

Version: 3.0

7. HANDLING AND STORAGE

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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Iron oxide

<table>
<thead>
<tr>
<th>Source</th>
<th>Limit Value (TWA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>2 ppm</td>
</tr>
<tr>
<td></td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>5.0 mg/m³</td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>3.5 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>3.5 mg/m³</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
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</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
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<td>Hungary OEL - TWA</td>
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<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>3.5 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>5 mg/m³</td>
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<tr>
<td>Portugal OEL - TWA</td>
<td>5 mg/m³</td>
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<tr>
<td>Romania OEL - TWA</td>
<td>5 mg/m³</td>
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<tr>
<td>Russia OEL - TWA</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>1.5 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>3.5 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>

Magnesium stearate

<table>
<thead>
<tr>
<th>Source</th>
<th>Limit Value (TWA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>

Hydrochlorothiazide

SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Pfizer OEL TWA-8 Hr: 250µg/m³

Titanium dioxide
- ACGIH Threshold Limit Value (TWA) 10 mg/m³
- ACGIH OELs - Notice of Intended Changes Listed
- Australia TWA 10 mg/m³
- Austria OEL - MAKs 5 mg/m³
- Belgium OEL - TWA 10 mg/m³
- Bulgaria OEL - TWA 10.0 mg/m³
- Denmark OEL - TWA 6 mg/m³
- Estonia OEL - TWA 5 mg/m³
- France OEL - TWA 10 mg/m³
- Greece OEL - TWA 10 mg/m³
- Ireland OEL - TWAs 10 mg/m³
- Latvia OEL - TWA 10 mg/m³
- Lithuania OEL - TWA 5 mg/m³
- OSHA - Final PELS - TWAs: 15 mg/m³
- Poland OEL - TWA 10.0 mg/m³
- Portugal OEL - TWA 10 mg/m³
- Romania OEL - TWA 10 mg/m³
- Russia OEL - TWA 10 mg/m³
- Spain OEL - TWA 10 mg/m³
- Sweden OEL - TWAs 5 mg/m³
- Switzerland OEL - TWAs 3 mg/m³
- Vietnam OEL - TWAs 6 mg/m³

Calcium sulfate, dihydrate
- ACGIH Threshold Limit Value (TWA) 10 mg/m³
- Germany (DFG) - MAK 1.5 mg/m³
- Germany (DFG) - MAK 4 mg/m³
- Portugal OEL - TWA 10 mg/m³
- Spain OEL - TWA 10 mg/m³
- Switzerland OEL - TWAs 3 mg/m³
- Vietnam OEL - TWAs 6 mg/m³

Spironolactone
- Pfizer OEL TWA-8 Hr: 90 µg/m³, Skin

Polyethylene glycol
- Austria OEL - MAKs 1000 mg/m³
- Germany - TRGS 900 - TWAs 1000 mg/m³
- Germany (DFG) - MAK 1000 mg/m³ average molecular weight 200-600
- Slovakia OEL - TWA 1000 mg/m³
- Slovenia OEL - TWA 1000 mg/m³
- Switzerland OEL - TWAs 1000 ppm

Corn Starch
- ACGIH Threshold Limit Value (TWA) 10 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Analytical Method:
Analytical method available for Spironolactone. Contact Pfizer Inc for further information.

Exposure Controls:
General room ventilation is adequate unless the process generates dust, mist or fumes. Engineering controls should be used as the primary means to control exposures. 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

Physical State: Film-coated tablets
Odor: No data available.
Color: Tan
Molecular Formula: Mixture
Odor Threshold: No data available.
Molecular Weight: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)

Povidone
No data available
Magnesium stearate
No data available
Corn Starch
No data available
Hydroxypropyl cellulose
No data available
Iron oxide

SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE
9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Titanium dioxide
No data available
Hydroxypropyl methylcellulose
No data available
Polyethylene glycol
No data available
Flavor
No data available
Calcium sulfate, dihydrate
No data available

Spironolactone
Predicted 7.4 Log D 3.12

Hydrochlorothiazide

No data available

Decomposition Temperature (°C): No data available.
Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): No data available
Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
Short Term: Antihypertensive drug: has blood pressure-lowering properties
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on blood, kidneys, reproductive system.
11. TOXICOLOGICAL INFORMATION

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. May cause adverse effects on the developing fetus.

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Species</th>
<th>Route</th>
<th>LD50</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Povidone</td>
<td>Rat</td>
<td>Oral</td>
<td>100 g/kg</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Rat</td>
<td>Oral</td>
<td>&gt;2000 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Inhalation</td>
<td>LC50 &gt;2000 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>Rat</td>
<td>Oral</td>
<td>&gt;7500 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>LD50 50 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>Rat</td>
<td>Oral</td>
<td>&gt;10,000 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Spironolactone</td>
<td>Rat</td>
<td>Oral</td>
<td>4121 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt;1000mg/kg</td>
<td></td>
</tr>
<tr>
<td>Rabbit</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt;1000mg/kg</td>
<td></td>
</tr>
<tr>
<td>Rat</td>
<td>Intraperitoneal</td>
<td>LD50 786mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrochlorothiazide</td>
<td>Rat</td>
<td>Oral</td>
<td>2750 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>LD50</td>
<td>2830mg/kg</td>
<td></td>
</tr>
<tr>
<td>Rat</td>
<td>Intravenous</td>
<td>LD50 990mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dog</td>
<td>Intravenous</td>
<td>LD50 250mg/kg</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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)

<table>
<thead>
<tr>
<th>Material</th>
<th>Study Type</th>
<th>Species</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyethylene glycol</td>
<td>Eye Irritation</td>
<td>Rabbit</td>
<td>Mild</td>
</tr>
<tr>
<td>Skin Irritation</td>
<td>Rabbit</td>
<td>Mild</td>
<td></td>
</tr>
<tr>
<td>Spironolactone</td>
<td>Skin Sensitization - GPMT</td>
<td>Guinea Pig</td>
<td>No effect</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spironolactone</td>
<td>13 Week(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>50 mg/kg</td>
<td>LOAEL</td>
<td>Blood</td>
</tr>
<tr>
<td></td>
<td>78 Week(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>50 mg/kg/day</td>
<td>LOAEL</td>
<td>Liver, Male reproductive system</td>
</tr>
</tbody>
</table>

Hydrochlorothiazide

SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE
11. TOXICOLOGICAL INFORMATION

### 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 NOAEL Fertility
- Embryo / Fetal Development: Mouse Intraperitoneal 100 mg/kg/day NOAEL Maternal Toxicity
- Embryo / Fetal Development: Rat Oral 50 mg/kg/day NOAEL Fetotoxicity
- Embryo / Fetal Development: Rabbit Oral 20 mg/kg/day NOAEL Fetotoxicity

**Hydrochlorothiazide**
- Reproductive & Fertility: Rat Oral 1000 mg/kg LOAEL Maternal toxicity
- Reproductive & Fertility: Mouse Oral 3000 mg/kg/day NOEL No effects at maximum dose
- Embryo / Fetal Development: Rat Oral 1000 mg/kg/day NOEL Not Teratogenic
- Embryo / Fetal Development: Mouse Oral 3000 mg/kg/day NOEL Not Teratogenic

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

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

**Hydrochlorothiazide**
- Bacterial Mutagenicity (Ames): *Salmonella* Negative
- *In Vitro* Sister Chromatid Exchange: Chinese Hamster Ovary (CHO) cells Positive
- *In Vitro* Chromosome Aberration: Chinese Hamster Ovary (CHO) cells Negative
- Dominant Lethal Assay: Drosophila Negative
- Mammalian Cell Mutagenicity: Mouse Lymphoma Positive

### 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

**Hydrochlorothiazide**
- 2 Year(s): Rat Oral 2000 ppm NOAEL Not carcinogenic
- 2 Year(s): Female Mouse Oral 5000 ppm NOAEL Not carcinogenic
- 2 Year(s): Male Mouse Oral 5000 ppm LOAEL Malignant tumors, Liver

**Carcinogen Status:** See below

**Povidone**
- IARC: Group 3 (Not Classifiable)
11. TOXICOLOGICAL INFORMATION

Iron oxide
IARC: Group 3 (Not Classifiable)

Titanium dioxide
IARC: Group 2B (Possibly Carcinogenic to Humans)

Spironolactone
IARC: Group 3 (Not Classifiable)

Hydrochlorothiazide
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)
Spironolactone Predicted 7.4 Log D 3.12

Mobility in Soil: No data available

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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

Iron oxide
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 215-168-2

Flavor
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
EU EINECS/ELINCS List Not Listed

Povidone
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List Not Listed

Magnesium stearate
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 209-150-3

Hydroxypropyl methylcellulose
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
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 Not Listed

Hydrochlorothiazide
### 15. REGULATORY INFORMATION

<table>
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<tr>
<th>Material Name</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
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<td>Spironolactone and Hydrochlorothiazide Tablets (Spironolactone and Hydrochlorothiazide)</td>
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<td>Titanium dioxide</td>
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<td>carcinogen initial date 9/2/11 airborne, unbound particles of respirable size</td>
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</tbody>
</table>
15. REGULATORY INFORMATION

REACH - Annex IV - Exemptions from the obligations of Register: Present
EU EINECS/ELINCS List: 232-679-6

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child
Carcinogenicity-Cat.2; H351 - Suspected of causing cancer
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure

Carcinogenic: Category 3
Toxic to Reproduction: Category 2
Xn - Harmful

R40 - Limited evidence of a carcinogenic effect
R61 - May cause harm to the unborn child.
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 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 12 - Ecological Information. Updated Section 11 - Toxicology Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information.

Revision date: 04-Mar-2015
Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet