



# SAFETY DATA SHEET

Revision date: 30-Jan-2014

Version: 2.0

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

### Product Identifier

**Material Name:** Eplerenone Tablets

**Trade Name:** INSPRA; SELARA

**Chemical Family:** Mixture

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

**Intended Use:** Pharmaceutical product used as cardiovascular drug

### 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:  
International CHEMTREC (24 hours): +1-703-527-3887

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** Not classified as hazardous

### EU Classification:

EU Indication of danger: Not classified

### Label Elements

### Other Hazards

No data available

### Australian Hazard Classification (NOHSC):

Non-Hazardous Substance. Non-Dangerous Goods.

### Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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 | GHS Classification | % |
|------------|------------|-----------------------|-------------------|--------------------|---|
|------------|------------|-----------------------|-------------------|--------------------|---|

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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

|                            |             |            |            |            |                |
|----------------------------|-------------|------------|------------|------------|----------------|
| Eplerenone                 | 107724-20-9 | Not Listed | Not Listed | Not Listed | 25 or 50 mg*** |
| Ferric oxide red           | 1309-37-1   | 215-168-2  | Not Listed | Not Listed | *              |
| Microcrystalline cellulose | 9004-34-6   | 232-674-9  | Not Listed | Not Listed | *              |
| Talc (non-asbestiform)     | 14807-96-6  | 238-877-9  | Not Listed | Not Listed | *              |
| Magnesium stearate         | 557-04-0    | 209-150-3  | Not Listed | Not Listed | *              |
| Polyethylene glycol        | 25322-68-3  | Not Listed | Not Listed | Not Listed | *              |
| Sodium lauryl sulfate      | 151-21-3    | 205-788-1  | Not Listed | Not Listed | *              |
| Titanium dioxide           | 13463-67-7  | 236-675-5  | Not Listed | Not Listed | *              |

| Ingredient                    | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|-------------------------------|------------|-----------------------|-------------------|--------------------|---|
| Ferric oxide yellow           | 51274-00-1 | 257-098-5             | Not Listed        | Not Listed         | * |
| Croscarmellose sodium         | 74811-65-7 | Not Listed            | Not Listed        | Not Listed         | * |
| Lactose                       | 63-42-3    | 200-559-2             | Not Listed        | Not Listed         | * |
| Polysorbate 80                | 9005-65-6  | Not Listed            | Not Listed        | Not Listed         | * |
| Hydroxypropyl methylcellulose | 9004-65-3  | Not Listed            | Not Listed        | Not Listed         | * |

**Additional Information:**

\* Proprietary  
\*\*\* per tablet/capsule/lozenge/suppository  
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.

### 4. FIRST AID MEASURES

**Description of First Aid Measures**

**Eye Contact:** Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

**Skin Contact:** Remove contaminated clothing and wash exposed area with soap and water. Obtain medical assistance if irritation occurs.

**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**

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**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

### 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

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):** No data available

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Control Parameters

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

### Eplerenone

Pfizer OEL TWA-8 Hr: 350 µg/m<sup>3</sup>

### Ferric oxide red

|                                   |                       |
|-----------------------------------|-----------------------|
| ACGIH Threshold Limit Value (TWA) | 5 mg/m <sup>3</sup>   |
| Australia TWA                     | 5 mg/m <sup>3</sup>   |
|                                   | 10 mg/m <sup>3</sup>  |
| Austria OEL - MAKs                | 5 mg/m <sup>3</sup>   |
|                                   | 10 mg/m <sup>3</sup>  |
| Belgium OEL - TWA                 | 2 ppm                 |
|                                   | 5 mg/m <sup>3</sup>   |
| Bulgaria OEL - TWA                | 5.0 mg/m <sup>3</sup> |
| Denmark OEL - TWA                 | 3.5 mg/m <sup>3</sup> |

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

|                                   |   |
|-----------------------------------|---|
| Estonia OEL - TWA                 | 3.5 mg/m <sup>3</sup>   |
| Finland OEL - TWA                 | 5 mg/m <sup>3</sup>   |
| France OEL - TWA                  | 5 mg/m <sup>3</sup>   |
| Greece OEL - TWA                  | 10 mg/m <sup>3</sup>  |
| Hungary OEL - TWA                 | 6 mg/m <sup>3</sup>   |
| Ireland OEL - TWAs                | 5 mg/m <sup>3</sup><br>10 mg/m <sup>3</sup><br>4 mg/m <sup>3</sup>          |
| Lithuania OEL - TWA               | 3.5 mg/m <sup>3</sup>   |
| OSHA - Final PELs - TWAs:         | 10 mg/m <sup>3</sup><br>15 mg/m <sup>3</sup>                                |
| Poland OEL - TWA                  | 5 mg/m <sup>3</sup>   |
| Portugal OEL - TWA                | 5 mg/m <sup>3</sup>   |
| Romania OEL - TWA                 | 5 mg/m <sup>3</sup>   |
| Russia OEL - TWA                  | 6 mg/m <sup>3</sup>   |
| Slovakia OEL - TWA                | 1.5 mg/m <sup>3</sup>   |
| Spain OEL - TWA                   | 5 mg/m <sup>3</sup>   |
| Sweden OEL - TWAs                 | 3.5 mg/m <sup>3</sup>   |
| Switzerland OEL - TWAs            | 3 mg/m <sup>3</sup>   |
| Vietnam OEL - TWAs                | 5 mg/m <sup>3</sup>   |
| <br>                              |   |
| <b>Microcrystalline cellulose</b> |   |
| ACGIH Threshold Limit Value (TWA) | 10 mg/m <sup>3</sup>  |
| Australia TWA                     | 10 mg/m <sup>3</sup>  |
| Belgium OEL - TWA                 | 10 mg/m <sup>3</sup>  |
| Estonia OEL - TWA                 | 10 mg/m <sup>3</sup>  |
| France OEL - TWA                  | 10 mg/m <sup>3</sup>  |
| Ireland OEL - TWAs                | 10 mg/m <sup>3</sup><br>4 mg/m <sup>3</sup>                                 |
| Latvia OEL - TWA                  | 2 mg/m <sup>3</sup>   |
| OSHA - Final PELs - TWAs:         | 15 mg/m <sup>3</sup>  |
| Portugal OEL - TWA                | 10 mg/m <sup>3</sup>  |
| Romania OEL - TWA                 | 10 mg/m <sup>3</sup>  |
| Russia OEL - TWA                  | 6 mg/m <sup>3</sup>   |
| Spain OEL - TWA                   | 10 mg/m <sup>3</sup>  |
| Switzerland OEL - TWAs            | 3 mg/m <sup>3</sup>   |
| Vietnam OEL - TWAs                | 10 mg/m <sup>3</sup><br>5 mg/m <sup>3</sup>                                 |
| <br>                              |   |
| <b>Talc (non-asbestiform)</b>     |   |
| ACGIH Threshold Limit Value (TWA) | 2 mg/m <sup>3</sup>   |
| Australia TWA                     | 2.5 mg/m <sup>3</sup>   |
| Austria OEL - MAKs                | 2 mg/m <sup>3</sup>   |
| Belgium OEL - TWA                 | 2 mg/m <sup>3</sup>   |
| Bulgaria OEL - TWA                | 1.0 fiber/cm <sup>3</sup><br>6.0 mg/m <sup>3</sup><br>3.0 mg/m <sup>3</sup> |
| Czech Republic OEL - TWA          | 2.0 mg/m <sup>3</sup>   |
| Denmark OEL - TWA                 | 0.3 fiber/cm <sup>3</sup>   |
| Finland OEL - TWA                 | 0.5 fiber/cm <sup>3</sup>   |
| Greece OEL - TWA                  | 10 mg/m <sup>3</sup><br>2 mg/m <sup>3</sup>                                 |

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|  |   |
|--|---|
| Hungary OEL - TWA                        | 2 mg/m <sup>3</sup>                                     |
| Ireland OEL - TWAs                       | 10 mg/m <sup>3</sup>                                    |
|  | 0.8 mg/m <sup>3</sup>                                   |
| Lithuania OEL - TWA                      | 2 mg/m <sup>3</sup>                                     |
|  | 1 mg/m <sup>3</sup>                                     |
| Netherlands OEL - TWA                    | 0.25 mg/m <sup>3</sup>                                  |
| OSHA - Final PELs - Table Z-3 Mineral D: | 20 mppcf  |
| Poland OEL - TWA                         | 4.0 mg/m <sup>3</sup>                                   |
|  | 1.0 mg/m <sup>3</sup>                                   |
| Portugal OEL - TWA                       | 2 mg/m <sup>3</sup>                                     |
| Romania OEL - TWA                        | 2 mg/m <sup>3</sup>                                     |
| Slovakia OEL - TWA                       | 2 mg/m <sup>3</sup>                                     |
|  | 10 mg/m <sup>3</sup>                                    |
| Slovenia OEL - TWA                       | 2 mg/m <sup>3</sup>                                     |
| Spain OEL - TWA                          | 2 mg/m <sup>3</sup>                                     |
| Sweden OEL - TWAs                        | 2 mg/m <sup>3</sup>                                     |
|  | 1 mg/m <sup>3</sup>                                     |
| Switzerland OEL -TWAs                    | 2 mg/m <sup>3</sup>                                     |
| <br>                                     |   |
| <b>Magnesium stearate</b>                |   |
| ACGIH Threshold Limit Value (TWA)        | 10 mg/m <sup>3</sup>                                    |
| Lithuania OEL - TWA                      | 5 mg/m <sup>3</sup>                                     |
| Sweden OEL - TWAs                        | 5 mg/m <sup>3</sup>                                     |
| <br>                                     |   |
| <b>Polyethylene glycol</b>               |   |
| Austria OEL - MAKs                       | 1000 mg/m <sup>3</sup>                                  |
| Germany - TRGS 900 - TWAs                | 1000 mg/m <sup>3</sup>                                  |
| Germany (DFG) - MAK                      | 1000 mg/m <sup>3</sup> average molecular weight 200-600 |
| Slovakia OEL - TWA                       | 1000 mg/m <sup>3</sup>                                  |
| Slovenia OEL - TWA                       | 1000 mg/m <sup>3</sup>                                  |
| Switzerland OEL -TWAs                    | 1000 ppm  |
| <br>                                     |   |
| <b>Sodium lauryl sulfate</b>             |   |
| Pfizer OEL TWA-8 Hr:                     | 0.3 mg/m <sup>3</sup>                                   |
| <br>                                     |   |
| <b>Titanium dioxide</b>                  |   |
| ACGIH Threshold Limit Value (TWA)        | 10 mg/m <sup>3</sup>                                    |
| ACGIH OELs - Notice of Intended Changes  | Listed  |
| Australia TWA                            | 10 mg/m <sup>3</sup>                                    |
| Austria OEL - MAKs                       | 5 mg/m <sup>3</sup>                                     |
| Belgium OEL - TWA                        | 10 mg/m <sup>3</sup>                                    |
| Bulgaria OEL - TWA                       | 10.0 mg/m <sup>3</sup>                                  |
| Denmark OEL - TWA                        | 6 mg/m <sup>3</sup>                                     |
| Estonia OEL - TWA                        | 5 mg/m <sup>3</sup>                                     |
| France OEL - TWA                         | 10 mg/m <sup>3</sup>                                    |
| Greece OEL - TWA                         | 10 mg/m <sup>3</sup>                                    |
|  | 5 mg/m <sup>3</sup>                                     |
| Ireland OEL - TWAs                       | 10 mg/m <sup>3</sup>                                    |
|  | 4 mg/m <sup>3</sup>                                     |
| Latvia OEL - TWA                         | 10 mg/m <sup>3</sup>                                    |
| Lithuania OEL - TWA                      | 5 mg/m <sup>3</sup>                                     |
| OSHA - Final PELs - TWAs:                | 15 mg/m <sup>3</sup>                                    |
| Poland OEL - TWA                         | 10.0 mg/m <sup>3</sup>                                  |

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

|                       |                      |
|-----------------------|----------------------|
| Portugal OEL - TWA    | 10 mg/m <sup>3</sup> |
| Romania OEL - TWA     | 10 mg/m <sup>3</sup> |
| Russia OEL - TWA      | 10 mg/m <sup>3</sup> |
| Spain OEL - TWA       | 10 mg/m <sup>3</sup> |
| Sweden OEL - TWAs     | 5 mg/m <sup>3</sup>  |
| Switzerland OEL -TWAs | 3 mg/m <sup>3</sup>  |
| Vietnam OEL - TWAs    | 6 mg/m <sup>3</sup>  |
|                       | 5 mg/m <sup>3</sup>  |

#### Exposure Controls

##### 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>    | Tablets            | <b>Color:</b>            | Yellow             |
| <b>Odor:</b>              | No data available. | <b>Odor Threshold:</b>   | No data available. |
| <b>Molecular Formula:</b> | Mixture            | <b>Molecular Weight:</b> | Mixture            |

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

#### Lactose

No data available

#### Talc (non-asbestiform)

No data available

#### Titanium dioxide

No data available

#### Polysorbate 80

No data available

#### Magnesium stearate

No data available

#### Microcrystalline cellulose

No data available

#### Croscarmellose sodium

No data available

#### Sodium lauryl sulfate

No data available

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Ferric oxide yellow

No data available

#### Ferric oxide red

No data available

#### Eplerenone

Measured 7 Log P 1.02

#### Hydroxypropyl methylcellulose

No data available

#### Polyethylene glycol

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:** May cause eye and skin irritation if tablets are crushed or broken (based on components) .  
Accidental ingestion may cause effects similar to those seen in clinical use.

**Known Clinical Effects:** Effects reported during clinical use include headache, dizziness, decrease in blood pressure (hypotension), increased potassium, nausea, diarrhea, and insomnia.

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

##### Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

##### Titanium dioxide

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

#### Polysorbate 80

Rat Oral LD50 25 g/kg

#### Magnesium stearate

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

#### Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg  
Rabbit Dermal LD50 > 2000 mg/kg

#### Sodium lauryl sulfate

Rat Oral LD50 1288 mg/kg

#### Eplerenone

Rat Oral Minimum Lethal Dose > 2000 mg/kg  
Mouse Oral Minimum Symptomatic Dose > 300mg/kg  
Dog Oral Minimum Symptomatic Dose 500mg/kg

#### 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)

##### Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Non-irritating

##### Sodium lauryl sulfate

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Mild Moderate  
Skin Sensitization - GPMT Guinea Pig Negative  
Skin Sensitization - LLNA Mouse Negative

##### Eplerenone

Eye Irritation Rabbit Minimal  
Skin Irritation Rabbit Mild  
Skin Sensitization - GPMT Guinea Pig Negative

##### Polyethylene glycol

Eye Irritation Rabbit Mild  
Skin Irritation Rabbit Mild

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

##### Eplerenone



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### 11. TOXICOLOGICAL INFORMATION

|            |     |      |               |       |                          |
|------------|-----|------|---------------|-------|--------------------------|
| 13 Week(s) | Rat | Oral | 500 mg/kg/day | LOAEL | Kidney                   |
| 13 Week(s) | Dog | Oral | 1.5 mg/kg/day | NOEL  | Male reproductive system |

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

##### **Eplerenone**

|                                |        |      |                |       |                                 |
|--------------------------------|--------|------|----------------|-------|---------------------------------|
| Reproductive & Fertility-Males | Rat    | Oral | 1000 mg/kg/day | LOAEL | Fertility                       |
| Embryo / Fetal Development     | Rat    | Oral | 1000 mg/kg/day | LOAEL | Maternal Toxicity, Fetotoxicity |
| Embryo / Fetal Development     | Rabbit | Oral | 300 mg/kg/day  | LOAEL | Maternal Toxicity, Fetotoxicity |
| Embryo / Fetal Development     | Rat    | Oral | 300 mg/kg/day  | NOAEL | No effects at maximum dose      |

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

##### **Sodium lauryl sulfate**

Bacterial Mutagenicity (Ames) *Salmonella* Negative

##### **Eplerenone**

Bacterial Mutagenicity (Ames) Negative  
Mammalian Cell Mutagenicity Mouse Lymphoma Negative  
Chromosome Aberration Negative  
Unscheduled DNA Synthesis Negative  
*In Vitro* Micronucleus Negative

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

##### **Eplerenone**

|            |            |      |                |      |                        |
|------------|------------|------|----------------|------|------------------------|
| 6 Month(s) | Mouse      | Oral | 1000 mg/kg/day | NOEL | Not carcinogenic       |
| 2 Year(s)  | Male Rat   | Oral | 75 mg/kg/day   | LOEL | Benign tumors, Thyroid |
| 2 Year(s)  | Female Rat | Oral | 250 mg/kg/day  | LOEL | Benign tumors, Thyroid |

**Carcinogen Status:** See below

##### **Talc (non-asbestiform)**

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

##### **Titanium dioxide**

**IARC:** Group 2B (Possibly Carcinogenic to Humans)  
**OSHA:** Listed

##### **Ferric oxide red**

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

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been investigated. Releases to the environment should be avoided. The following information is available for the individual ingredients.

**Toxicity:**

**Aquatic Toxicity: (Species, Method, End Point, Duration, Result)**

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### Sodium lauryl sulfate

*Oncorhynchus mykiss* (Rainbow Trout) LC50 96 Hours 3.6 mg/L

### Eplerenone

*Daphnia magna* (Water Flea) TAD EC50 48 Hours > 380 mg/L

*Pimephales promelas* (Fathead Minnow) TAD LC50 96 Hours > 370 mg/L

*Pseudokirchneriella subcapitata* (Green Alga) OECD ErC50/0-72hr (OECD) Hours > 10 mg/L

*Pseudokirchneriella subcapitata* (Green Alga) TAD NOEC 12 Days > 10 mg/L

**Aquatic Toxicity Comments:** A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

### Bacterial Inhibition: (Inoculum, Method, End Point, Result)

#### Eplerenone

Bacteria OECD EC50 > 1000 mg/L

### Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

#### Eplerenone

*Pimephales promelas* (Fathead Minnow) OECD 32 Day(s) NOEC 1 mg/L Survival Growth

*Daphnia magna* (Water Flea) OECD 21 Day(s) NOEC 2.9 mg/L Reproduction

**Persistence and Degradability:** No data available

#### Eplerenone

OECD Activated sludge Ultimate (CO2 Evolution) -2.8% After 28 Day(s) Not Ready

**Bio-accumulative Potential:** No data available

#### Eplerenone

Measured 7 Log P 1.02

**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.

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### 15. REGULATORY INFORMATION

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

##### Canada - WHMIS: Classifications

###### WHMIS hazard class:

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

##### **Eplerenone**

|   |            |
|---|------------|
| <b>CERCLA/SARA 313 Emission reporting</b>                             | Not Listed |
| <b>California Proposition 65</b>                                      | Not Listed |
| <b>Standard for the Uniform Scheduling<br/>for Drugs and Poisons:</b> | Schedule 4 |
| <b>EU EINECS/ELINCS List</b>  | Not Listed |

##### **Ferric oxide yellow**

|  |            |
|--|------------|
| <b>CERCLA/SARA 313 Emission reporting</b>          | Not Listed |
| <b>California Proposition 65</b>                   | Not Listed |
| <b>Inventory - United States TSCA - Sect. 8(b)</b> | Present    |
| <b>Australia (AICS):</b>                           | Present    |
| <b>EU EINECS/ELINCS List</b>                       | 257-098-5  |

##### **Ferric oxide red**

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

##### **Microcrystalline cellulose**

|  |            |
|--|------------|
| <b>CERCLA/SARA 313 Emission reporting</b>          | Not Listed |
| <b>California Proposition 65</b>                   | Not Listed |
| <b>Inventory - United States TSCA - Sect. 8(b)</b> | Present    |
| <b>Australia (AICS):</b>                           | Present    |
| <b>EU EINECS/ELINCS List</b>                       | 232-674-9  |

##### **Croscarmellose sodium**

|   |            |
|---|------------|
| <b>CERCLA/SARA 313 Emission reporting</b> | Not Listed |
| <b>California Proposition 65</b>          | Not Listed |
| <b>Australia (AICS):</b>                  | Present    |
| <b>EU EINECS/ELINCS List</b>              | Not Listed |

##### **Lactose**

|  |            |
|--|------------|
| <b>CERCLA/SARA 313 Emission reporting</b>          | Not Listed |
| <b>California Proposition 65</b>                   | Not Listed |
| <b>Inventory - United States TSCA - Sect. 8(b)</b> | Present    |
| <b>Australia (AICS):</b>                           | Present    |

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**15. REGULATORY INFORMATION**

|   |            |
|---|------------|
| REACH - Annex IV - Exemptions from the obligations of Register: | Present    |
| EU EINECS/ELINCS List   | 200-559-2  |
| <b>Talc (non-asbestiform)</b>                                   |            |
| 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   | 238-877-9  |
| <b>Polysorbate 80</b>   |            |
| 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 |
| <b>Magnesium stearate</b>                                       |            |
| 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  |
| <b>Hydroxypropyl methylcellulose</b>                            |            |
| 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 |
| <b>Polyethylene glycol</b>                                      |            |
| 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 3 |
| EU EINECS/ELINCS List   | Not Listed |
| <b>Sodium lauryl sulfate</b>                                    |            |
| 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 6 |
| EU EINECS/ELINCS List   | 205-788-1  |
| <b>Titanium dioxide</b>   |            |

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### 15. REGULATORY INFORMATION

|   |   |
|---|---|
| CERCLA/SARA 313 Emission reporting<br>California Proposition 65 | Not Listed<br>carcinogen initial date 9/2/11 airborne, unbound particles of respirable size |
| Inventory - United States TSCA - Sect. 8(b)                     | Present   |
| Australia (AICS):   | Present   |
| EU EINECS/ELINCS List   | 236-675-5   |

### 16. OTHER INFORMATION

|                              |   |
|------------------------------|---|
| <b>Data Sources:</b>         | Pfizer proprietary drug development information. Publicly available toxicity information.   |
| <b>Reasons for Revision:</b> | Updated Section 2 - Hazard Identification. Updated Section 9 - Physical and Chemical Properties. Updated Section 11 - Toxicology Information. |
| <b>Revision date:</b>        | 30-Jan-2014<br>Product Stewardship Hazard Communication   |
| <b>Prepared by:</b>          | Pfizer Global Environment, Health, and Safety Operations  |

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**End of Safety Data Sheet**