MATERIAL SAFETY DATA SHEET

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: Eplerenone Tablets

Trade Name: INSPRA; SELARA
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as cardiovascular drug

2. HAZARDS IDENTIFICATION

Appearance: White tablets

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:
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.

EU Indication of danger: Not classified

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

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	%
Eplerenone	107724-20-9	Not Listed	Not Listed	25 or 50 mg***
Ferric oxide red	1309-37-1	215-168-2	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*

3. COMPOSITION/INFORMATION ON INGREDIENTS

Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	*
Sodium lauryl sulfate	151-21-3	205-788-1	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*

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

4. 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.

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: Formation of toxic gases is possible during heating or fire.

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

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

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.

Eplerenone

Pfizer OEL TWA-8 Hr:	350 µg/m^3

Ferric oxide red

ACGIH Threshold Limit Value (TWA)	5 mg/m^3
Australia TWA	5 mg/m^3 10 mg/m^3
Austria OEL - MAKs	5 mg/m^3 10 mg/m^3
Belgium OEL - TWA	2 ppm 5 mg/m^3
Bulgaria OEL - TWA	5.0 mg/m^3
Denmark OEL - TWA	3.5 mg/m^3
Estonia OEL - TWA	3.5 mg/m^3
Finland OEL - TWA	5 mg/m^3
France OEL - TWA	5 mg/m^3
Greece OEL - TWA	10 mg/m^3
Hungary OEL - TWA	6 mg/m^3
Ireland OEL - TWAs	5 mg/m^3 10 mg/m^3 4 mg/m^3
Lithuania OEL - TWA	3.5 mg/m^3
OSHA - Final PELS - TWAs:	10 mg/m^3 15 mg/m^3
Poland OEL - TWA	5 mg/m^3
Portugal OEL - TWA	5 mg/m^3
Romania OEL - TWA	5 mg/m^3
Slovakia OEL - TWA	1.5 mg/m^3
Spain OEL - TWA	5 mg/m^3
Sweden OEL - TWAs	3.5 mg/m^3

Microcrystalline cellulose

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Australia TWA	10 mg/m^3
Belgium OEL - TWA	10 mg/m^3
Estonia OEL - TWA	10 mg/m^3
France OEL - TWA	10 mg/m^3
Ireland OEL - TWAs	10 mg/m^3
	4 mg/m^3
Latvia OEL - TWA	2 mg/m^3
OSHA - Final PELS - TWAs:	15 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Spain OEL - TWA	10 mg/m^3

Talc (non-asbestiform)

ACGIH Threshold Limit Value (TWA)	2 mg/m^3
Australia TWA	2.5 mg/m^3
Austria OEL - MAKs	2 mg/m^3
Belgium OEL - TWA	2 mg/m^3
Bulgaria OEL - TWA	1.0 fiber/cm3
	6.0 mg/m^3
	3.0 mg/m^3
Czech Republic OEL - TWA	2.0 mg/m^3
	10 mg/m^3
Denmark OEL - TWA	0.3 fiber/cm3
Finland OEL - TWA	0.5 fiber/cm3
Greece OEL - TWA	10 mg/m^3
	2 mg/m^3
Hungary OEL - TWA	2 mg/m^3
Ireland OEL - TWAs	10 mg/m^3
	0.8 mg/m^3
Lithuania OEL - TWA	2 mg/m^3
	1 mg/m^3
Netherlands OEL - TWA	0.25 mg/m^3
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
Poland OEL - TWA	4.0 mg/m^3
	1.0 mg/m^3
Portugal OEL - TWA	2 mg/m^3
Slovakia OEL - TWA	2 mg/m^3
	10 mg/m^3
Slovenia OEL - TWA	2 mg/m^3
Spain OEL - TWA	2 mg/m^3
Sweden OEL - TWAs	2 mg/m^3
	1 mg/m^3

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 average molecular weight 200-600
Slovakia OEL - TWA	1000 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Slovenia OEL - TWA	1000 mg/m^3

Sodium lauryl sulfate

Pfizer OEL TWA-8 Hr:	0.3 mg/m^3

Titanium dioxide

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Australia TWA	10 mg/m^3
Austria OEL - MAKs	5 mg/m^3
Belgium OEL - TWA	10 mg/m^3
Bulgaria OEL - TWA	10.0 mg/m^3
Denmark OEL - TWA	6 mg/m^3
Estonia OEL - TWA	5 mg/m^3
France OEL - TWA	10 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
Latvia OEL - TWA	10 mg/m^3
Lithuania OEL - TWA	5 mg/m^3
OSHA - Final PELS - TWAs:	15 mg/m^3
Poland OEL - TWA	10.0 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Romania OEL - TWA	10 mg/m^3
Spain OEL - TWA	10 mg/m^3
Sweden OEL - TWAs	5 mg/m^3

Analytical Method:	Analytical method available for Eplerenone. 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:	Tablets	**Color:**	White
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
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

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)

Lactose
Rat Oral LD50 > 10 g/kg

Talc (non-asbestiform)
Rat Oral LD50 > 1600 mg/kg

Titanium dioxide
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^3

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 > 300 mg/kg
Dog Oral Minimum Symptomatic Dose 500 mg/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

11. TOXICOLOGICAL INFORMATION

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
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 LOEL Benign tumors, Thyroid

Carcinogen Status: See below

Talc (non-asbestiform)
IARC: Group 3 (Not Classifiable)

11. TOXICOLOGICAL INFORMATION

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.

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

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 3 Hours > 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

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 Indication of danger: Not classified

OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

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

California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

Ferric oxide yellow

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	257-098-5

Ferric oxide red

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

Microcrystalline cellulose

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-674-9

Croscarmellose sodium

California Proposition 65	Not Listed
Australia (AICS):	Present

Lactose

California Proposition 65	Not Listed

15. REGULATORY INFORMATION

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	200-559-2

Talc (non-asbestiform)

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	238-877-9

Polysorbate 80

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

Magnesium stearate

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

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

Polyethylene glycol

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

Sodium lauryl sulfate

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

Titanium dioxide

California Proposition 65	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

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 12 - Ecological Information. Updated Section 7 - Handling and Storage.

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