



MATERIAL SAFETY DATA SHEET

Revision date: 11-Oct-2007

Version: 1.3

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

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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

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Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Eplerenone	107724-20-9	Not listed	Not Listed	25 or 50 mg***
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Ferric oxide red	1309-37-1	215-168-2	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Polyethylene glycol	25322-68-3	Not listed	Not Listed	*
Sodium lauryl sulfate	151-21-3	205-788-1	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9 EEC No. 456-230-0	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Hypromellose	9004-65-3	Not listed	Not Listed	*
Polysorbate 80	9005-65-6	Not listed	Not Listed	*
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	*

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:

Not determined

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.

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- 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).
- Storage Conditions:** Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

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/m³

Titanium dioxide

ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA
Australia TWA	= 10 mg/m ³ TWA
Austria OEL - MAKs	= 6 mg/m ³ MAK
Belgium OEL - TWA	= 10 mg/m ³ TWA
Bulgaria OEL - TWA	= 10.0 mg/m ³ TWA
Denmark OEL - TWA	= 6 mg/m ³ TWA
Estonia OEL - TWA	= 5 mg/m ³ TWA
France OEL - TWA	= 10 mg/m ³ VME
Greece OEL - TWA	= 10 mg/m ³ TWA
	= 5 mg/m ³ TWA
Ireland OEL - TWAs	= 10 mg/m ³ TWA
	= 4 mg/m ³ TWA
Latvia OEL - TWA	= 10 mg/m ³ TWA
Lithuania OEL - TWA	= 5 mg/m ³ IPRV
Netherlands OEL - TWA	= 10 mg/m ³ MAC
OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA total
Poland OEL - TWA	= 10.0 mg/m ³ NDS <2% free crystalline silica and containing no asbestos
Portugal OEL - TWA	= 10 mg/m ³ TWA
Romania OEL - TWA	= 10 mg/m ³ TWA
Spain OEL - TWA	= 10 mg/m ³ VLA-ED
Sweden OEL - TWAs	= 5 mg/m ³ LLV

Ferric oxide red

ACGIH Threshold Limit Value (TWA)	= 5 mg/m ³ TWA
Australia TWA	= 5 mg/m ³ TWA
Austria OEL - MAKs	= 6 mg/m ³ MAK

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Belgium OEL - TWA	= 5 mg/m ³ TWA
Bulgaria OEL - TWA	= 5.0 mg/m ³ TWA
Denmark OEL - TWA	= 3.5 mg/m ³ TWA
Estonia OEL - TWA	= 3.5 mg/m ³ TWA
Finland OEL - TWA	= 5 mg/m ³ TWA
France OEL - TWA	= 5 mg/m ³ VME
Greece OEL - TWA	= 10 mg/m ³ TWA
Hungary OEL - TWA	= 6 mg/m ³ TWA
Ireland OEL - TWAs	= 10 mg/m ³ TWA
	= 4 mg/m ³ TWA
	= 5 mg/m ³ TWA
Lithuania OEL - TWA	= 3.5 mg/m ³ IPRV
Netherlands OEL - TWA	= 5 mg/m ³ MAC
OSHA - Final PELS - TWAs:	= 10 mg/m ³ TWA
Poland OEL - TWA	= 5 mg/m ³ NDS
Portugal OEL - TWA	= 5 mg/m ³ TWA
Romania OEL - TWA	= 5 mg/m ³ TWA
Slovakia OEL - TWA	= 1.5 mg/m ³ TWA
Spain OEL - TWA	= 5 mg/m ³ VLA-ED
Sweden OEL - TWAs	= 3.5 mg/m ³ LLV
Microcrystalline cellulose	
ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA
Australia TWA	= 10 mg/m ³ TWA
Belgium OEL - TWA	= 10 mg/m ³ TWA
Estonia OEL - TWA	= 10 mg/m ³ TWA
France OEL - TWA	= 10 mg/m ³ VME
Ireland OEL - TWAs	= 10 mg/m ³ TWA
	= 4 mg/m ³ TWA
Latvia OEL - TWA	= 2 mg/m ³ TWA
OSHA - Final PELS - TWAs:	= 15 mg/m ³ TWA total
	= 5 mg/m ³ TWA
Portugal OEL - TWA	= 10 mg/m ³ TWA
Romania OEL - TWA	= 10 mg/m ³ TWA
Spain OEL - TWA	= 10 mg/m ³ VLA-ED
Polyethylene glycol	
Austria OEL - MAKs	= 1000 mg/m ³ MAK
Germany - TRGS 900 - TWAs	= 1000 mg/m ³ TWA
Netherlands OEL - TWA	= 1000 mg/m ³ MAC
Slovakia OEL - TWA	= 1000 mg/m ³ TWA
Slovenia OEL - TWA	= 1000 mg/m ³ TWA
Sodium lauryl sulfate	
Pfizer OEL TWA-8 Hr:	0.3 mg/m ³
Pfizer STEL	0.75 mg/m ³
Talc (non-asbestiform)	
ACGIH Threshold Limit Value (TWA)	= 2 mg/m ³ TWA particulate matter containing no asbestos and <1% crystalline silica
ACGIH OELs - Notice of Intended Changes	Listed
Australia TWA	= 2.5 mg/m ³ TWA containing no asbestos fibers
Austria OEL - MAKs	= 2 mg/m ³ MAK asbestos-free fibers
Belgium OEL - TWA	= 2 mg/m ³ TWA

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Bulgaria OEL - TWA	= 1.0 f/cm ³ TWA containing <2% uncombined crystalline silicon dioxide
	= 3.0 mg/m ³ TWA
	= 6.0 mg/m ³ TWA
Czech Republic OEL - TWA	= 10 mg/m ³ TWA
	= 2.0 mg/m ³ TWA
Denmark OEL - TWA	= 0.3 fiber/cm ³ TWA
Estonia OEL - TWA	= 0.5 mg/m ³ TWA
	= 1 mg/m ³ TWA
Finland OEL - TWA	= 0.5 fibers/cm ³ TWA
	= 5 mg/m ³ TWA
Greece OEL - TWA	= 10 mg/m ³ TWA
	= 2 mg/m ³ TWA
Hungary OEL - TWA	= 2 mg/m ³ TWA
Ireland OEL - TWAs	= 0.8 mg/m ³ TWA
	= 10 mg/m ³ TWA
Netherlands OEL - TWA	= 1 mg/m ³ MAC
OSHA - Final PELs - Table Z-3 Mineral D:	= 20 mppcf TWA
Poland OEL - TWA	= 1.0 mg/m ³ NDS
	= 4.0 mg/m ³ NDS
Portugal OEL - TWA	= 2 mg/m ³ TWA
Romania OEL - TWA	= 2 mg/m ³ TWA
Slovakia OEL - TWA	= 10 mg/m ³ TWA
	= 2 mg/m ³ TWA
Slovenia OEL - TWA	= 2 mg/m ³ TWA
Spain OEL - TWA	= 2 mg/m ³ VLA-ED this value is for the particulated matter that is free from asbestos and contains less than 1% of crystalline silica
	= 1 mg/m ³ LLV
Sweden OEL - TWAs	= 2 mg/m ³ LLV

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA except stearates of toxic metals
Australia TWA	= 10 mg/m ³ TWA
Belgium OEL - TWA	= 10 mg/m ³ TWA
Ireland OEL - TWAs	= 10 mg/m ³ TWA except lead stearate
Lithuania OEL - TWA	= 3 mg/m ³ IPRV
Portugal OEL - TWA	= 10 mg/m ³ TWA does not include stearates of toxic metals
Spain OEL - TWA	= 10 mg/m ³ VLA-ED not including stearates of toxic metals
Sweden OEL - TWAs	= 5 mg/m ³ LLV

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

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.

Personal Protective Equipment:

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.

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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:	Tablets	Color:	White
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable at normal conditions
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)

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 LD 50 50 mg/kg

Polysorbate 80

Rat Oral LD50 25 g/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

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

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Dog Oral Minimum Symptomatic Dose 500 mg/kg

Hypromellose

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 Severe

Skin Irritation Rabbit Severe

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)

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

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Carcinogen Status: See below

Talc (non-asbestiform)

IARC: Group 3

Titanium dioxide

IARC: Group 2B

OSHA: Present

Ferric oxide red

IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided. See Aquatic toxicity data of the active ingredient, below:

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

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 EbC50 72 Hours 0.24 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: (Species, Method, End Point, Duration, Result)

Eplerenone

Bacteria OECD EC50 3 Hours > 1000 mg/L

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

14. TRANSPORT INFORMATION

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

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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

Standard for the Uniform Scheduling
for Drugs and Poisons: Schedule 4

Hypromellose

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

Titanium dioxide

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

Polysorbate 80

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

Ferric oxide yellow

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
Standard for the Uniform Scheduling
for Drugs and Poisons: Schedule 2
Schedule 4
Schedule 5
Schedule 6
EU EINECS/ELINCS List 257-098-5

Ferric oxide red

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
Standard for the Uniform Scheduling
for Drugs and Poisons: Schedule 2
Schedule 4
Schedule 5
Schedule 6

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EU EINECS/ELINCS List	215-168-2
Microcrystalline cellulose	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS/ELINCS List	232-674-9
Croscarmellose sodium	
Australia (AICS):	Present
Polyethylene glycol	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Sodium lauryl sulfate	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	205-788-1
Lactose	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-559-2
Talc (non-asbestiform)	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	238-877-9 EEC No. 456-230-0
Magnesium stearate	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

16. OTHER INFORMATION

Data Sources:	Pfizer proprietary drug development information. Publicly available toxicity information.
Reasons for Revision:	Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 12 - Ecological 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. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet