

Revision date: 07-Aug-2018 Version: 3.1 Page 1 of 13

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture GHS - Classification

Reproductive Toxicity: Category 1B Carcinogenicity: Category 2

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



Material Name: Spironolactone and Hydrochlorothiazide Page 2 of 13

Tablets

Revision date: 07-Aug-2018 Version: 3.1

Other Hazards An Occupational Exposure Value has been established for one or more of the ingredients (see

Section 8).

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	GHS Classification	%
		List		
Iron oxide	1309-37-1	215-168-2	Not Listed	*
Hydrochlorothiazide	58-93-5	200-403-3	Not Listed	>1
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Calcium sulfate, dihydrate	10101-41-4	Not Listed	Not Listed	*
Corn Starch	9005-25-8	232-679-6	Not Listed	*
Spironolactone	52-01-7	200-133-6	Carc.2 (H351) STOT RE.2 (H373) Repr.1B (H360D)	<10
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Flavor	NOT ASSIGNED	Not Listed	Not Listed	*
Povidone	9003-39-8	Not Listed	Not Listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	*
Hydroxypropyl cellulose	9004-64-2	Not Listed	Not Listed	*

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 CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Material Name: Spironolactone and Hydrochlorothiazide Page 3 of 13

Tablets

Revision date: 07-Aug-2018 Version: 3.1

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 For information on potential signs and symptoms of exposure, See Section 2 - Hazards

Exposure: Identification and/or Section 11 - Toxicological Information.

Medical Conditions None known

Aggravated by Exposure:

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 Toxic or corrosive gases including oxides of carbon and oxides of sulfur

Products:

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

During all firefighting 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 / Contain

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. Cleanup 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): Pharmaceutical drug product

Material Name: Spironolactone and Hydrochlorothiazide Page 4 of 13

Tablets

Revision date: 07-Aug-2018 Version: 3.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Iron oxide

ACGIH Threshold Limit Value (TWA) Australia TWA	5 mg/m³ 5 mg/m³ 10 mg/m³
Austria OEL - MAKs	5 mg/m³ 10 mg/m³
Belgium OEL - TWA	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
Russia OEL - TWA	6 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
Switzerland OEL -TWAs	3 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³

Hydrochlorothiazide

250µg/m³ Pfizer OEL TWA-8 Hr:

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/m³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m³
Latvia OEL - TWA	10 mg/m ³
Lithuania OEL - TWA	5 mg/m ³

Material Name: Spironolactone and Hydrochlorothiazide Page 5 of 13

Tablets

Revision date: 07-Aug-2018 Version: 3.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 10 mg/m³ **Russia OEL - TWA** 10 mg/m³ Spain OEL - TWA 5 mg/m³ **Sweden OEL - TWAs Switzerland OEL -TWAs** 3 mg/m^3 Vietnam OEL - TWAs 6 mg/m³

5 mg/m³

Calcium sulfate, dihydrate

ACGIH Threshold Limit Value (TWA) 10 mg/m³ **Belgium OEL - TWA** 10 mg/m³ Germany (DFG) - MAK 1.5 mg/m³ 4 mg/m³ Portugal OEL - TWA 10 mg/m³

10 mg/m³ Spain OEL - TWA **Switzerland OEL -TWAs** 3 mg/m^3 6 mg/m³ Vietnam OEL - TWAs

Corn Starch

ACGIH Threshold Limit Value (TWA) 10 mg/m³ 10 mg/m³ **Australia TWA** 10 mg/m³ **Belgium OEL - TWA Bulgaria OEL - TWA** 10.0 mg/m³ 4.0 mg/m³ Czech Republic OEL - TWA 10 mg/m³ **Greece OEL - TWA** 5 mg/m³

Ireland OEL - TWAs 10 mg/m³ 4 mg/m^3 **OSHA - Final PELS - TWAs:** 15 mg/m³ Portugal OEL - TWA 10 mg/m³ 4 mg/m^3 Slovakia OEL - TWA Spain OEL - TWA 10 ma/m³ **Switzerland OEL -TWAs** 3 mg/m^3

Spironolactone

Pfizer OEL TWA-8 Hr: 90 µg/m³, Skin

Magnesium stearate

Lithuania OEL - TWA 5 mg/m³ **Sweden OEL - TWAs** 5 mg/m³

Polyethylene glycol

Austria OEL - MAKs 1000 mg/m³ 1000 mg/m³ Germany - TRGS 900 - TWAs

Germany (DFG) - MAK 1000 mg/m³ average molecular weight 200-600

Slovakia OEL - TWA 1000 mg/m³ 1000 mg/m³ Slovenia OEL - TWA **Switzerland OEL -TWAs** 1000 mg/m³

Material Name: Spironolactone and Hydrochlorothiazide Page 6 of 13

Tablets

Revision date: 07-Aug-2018 Version: 3.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Controls

General room ventilation is adequate unless the process generates dust, mist or fumes. **Engineering Controls:**

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

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment **Equipment:**

supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and

specific operational processes.

Hands: Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug

product is possible and for bulk processing operations. (Protective gloves must meet the

standards in accordance with EN374, ASTM F1001 or international equivalent.)

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the Eyes:

standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Wear impervious protective clothing to prevent skin contact – consider use of disposable Skin:

clothing where appropriate. (Protective clothing must meet the standards in accordance with

EN13982, ANSI 103 or international equivalent.)

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is Respiratory protection:

> exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

> > **Molecular Weight:**

Mixture

9. PHYSICAL AND CHEMICAL PROPERTIES

Film-coated tablets **Physical State:** Color: Tan

No data available. Odor: No data available. Odor Threshold:

Molecular Formula: Mixture

Solvent Solubility: No data available No data available Water Solubility: pH: No data available. No data available **Melting/Freezing Point (°C): 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

No data available Titanium dioxide

No data available

Hydroxypropyl methylcellulose

No data available Polyethylene glycol

No data available

Flavor

Material Name: Spironolactone and Hydrochlorothiazide Page 7 of 13

Tablets

Revision date: 07-Aug-2018 Version: 3.1

9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Calcium sulfate, dihydrate

No data available **Spironolactone**

Predicted 7.4 Log D 3.12

HydrochlorothiazideNo data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s):

Vapor Pressure (kPa):

Vapor Density (g/ml):

Relative Density:

Viscosity:

No data available

No data available

No data available

No data available

Flammablity:

Autoignition Temperature (Solid) (°C):

Flammability (Solids):

Flash Point (Liquid) (°C):

Upper Explosive Limits (Liquid) (% by Vol.):

Lower Explosive Limits (Liquid) (% by Vol.):

No data available
No data available
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 No data available

Products:

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.

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)

Povidone

Rat Oral LD50 100 g/kg

Material Name: Spironolactone and Hydrochlorothiazide Page 8 of 13

Tablets

Revision date: 07-Aug-2018 Version: 3.1

11. TOXICOLOGICAL INFORMATION

Magnesium stearate

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

Titanium dioxide

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

Hydroxypropyl methylcellulose

Rat Oral LD50 > 10,000 mg/kg

Spironolactone

Rat Oral LD 50 4121 mg/kg

Mouse Oral LD 50 >1000mg/kg

Rabbit Oral LD 50 >1000mg/kg

Rat Intraperitoneal LD 50 786mg/kg

Hydrochlorothiazide

Rat Oral LD 50 2750 mg/kg Mouse Oral LD 50 2830mg/kg Rat Intravenous LD 50 990mg/kg Dog Intravenous LD 50 250mg/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)

Polyethylene glycol

Eye Irritation Rabbit Mild Skin Irritation Rabbit Mild

Spironolactone

Skin Sensitization - GPMT Guinea Pig No effect

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

Spironolactone

13 Week(s) Rat Oral 50 mg/kg LOAEL Blood

78 Week(s) Rat Oral 50 mg/kg/day LOAEL Liver, Male reproductive system

Hydrochlorothiazide

30 Day(s) Rat Oral 1 g/kg/day LOAEL Blood

13 Week(s) Mouse Oral 12,500 ppm LOAEL Bladder

9 Month(s) Dog Oral 50 mg/kg/day LOAEL Endocrine system

1 Year(s) Rat Oral 2000 ppm LOAEL Kidney

2 Year(s) Rat Oral 250 ppm LOAEL Kidney

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

Material Name: Spironolactone and Hydrochlorothiazide Page 9 of 13

Tablets

Revision date: 07-Aug-2018 Version: 3.1

11. TOXICOLOGICAL INFORMATION

Spironolactone

Reproductive & Fertility Rat Oral 15 mg/kg/day NOAEL Fetotoxicity

Reproductive & Fertility Rat Intraperitoneal 100 mg/kg/day LOAEL Fertility

Embryo / Fetal Development Mouse Intraperitoneal 100 mg/kg/day LOAEL Maternal Toxicity

Embryo / Fetal Development Rat Oral 50 mg/kg/day LOAEL Fetotoxicity Embryo / Fetal Development Rabbit Oral 20 mg/kg/day LOAEL Fetotoxicity

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)

Iron oxide

IARC: Group 3 (Not Classifiable)

Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)

Spironolactone

IARC: Group 3 (Not Classifiable)

Material Name: Spironolactone and Hydrochlorothiazide Page 10 of 13

Tablets

Revision date: 07-Aug-2018 Version: 3.1

11. TOXICOLOGICAL INFORMATION

Hydrochlorothiazide

IARC: Group 2B (Possibly Carcinogenic to Humans)

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

Material Name: Spironolactone and Hydrochlorothiazide Page 11 of 13

Tablets

Revision date: 07-Aug-2018 Version: 3.1

15. REGULATORY INFORMATION

Iron oxide

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Listed

Not Listed

Present

215-168-2

Flavor

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed

Not Listed

Povidone

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Hydroxypropyl methylcellulose

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Standard for the Uniform Scheduling

Not Listed

Not Listed

Not Listed

Present

Present

Schedule 4

for Drugs and Poisons:

EU EINECS/ELINCS List Not Listed

Hydrochlorothiazide

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Standard for the Uniform Scheduling

Schedule 4

for Drugs and Poisons:

EU EINECS/ELINCS List 200-403-3

Hydroxypropyl cellulose

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Titanium dioxide

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65 carcinogen 9/2/2011 airborne, unbound particles of respirable size

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

Material Name: Spironolactone and Hydrochlorothiazide Page 12 of 13

Tablets

Revision date: 07-Aug-2018 Version: 3.1

15. REGULATORY INFORMATION

EU EINECS/ELINCS List 236-675-5

Calcium sulfate, dihydrate

CERCLA/SARA 313 Emission reporting

California Proposition 65

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Listed

Corn Starch

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

REACH - Annex IV - Exemptions from the

Present

Present

obligations of Register:

EU EINECS/ELINCS List 232-679-6

Spironolactone

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65 carcinogen 5/1/1997

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Standard for the Uniform Scheduling

Present
Schedule 4

for Drugs and Poisons:

EU EINECS/ELINCS List 200-133-6

Magnesium stearate

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Present

209-150-3

Polyethylene glycol

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Standard for the Uniform Scheduling
for Drugs and Poisons:

EU EINECS/ELINCS List

Not Listed

16. OTHER INFORMATION

Text of CLP/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

Material Name: Spironolactone and Hydrochlorothiazide Page 13 of 13

Tablets

Prepared by:

Revision date: 07-Aug-2018 Version: 3.1

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 1 - Identification of the

Substance/Preparation and the Company/Undertaking. Updated Section 8 - Exposure Controls

/ Personal Protection.

Revision date: 07-Aug-2018

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