



SAFETY DATA SHEET

Revision date: 04-Mar-2015

Version: 3.0

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

Product Identifier

Material Name: Spironolactone and Hydrochlorothiazide Tablets

Trade Name: Aldactazide; Aldactone HCT; Aldazida; Aldactazida

Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used as antihypertensive, diuretic

Details of the Supplier of the Safety Data Sheet

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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

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

EU Classification:

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

EU Risk Phrases:

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

Label Elements

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

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

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Other Hazards No data available
Australian Hazard Classification (NOHSC): 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	%
Iron oxide	1309-37-1	215-168-2	Not Listed	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	Not Listed	*
Hydrochlorothiazide	58-93-5	200-403-3	Not Listed	Not Listed	>1
Titanium dioxide	13463-67-7	236-675-5	Not Listed	Not Listed	*
Calcium sulfate, dihydrate	10101-41-4	Not Listed	Not Listed	Not Listed	*
Spironolactone	52-01-7	200-133-6	Repr.Cat.2;R61 Carc.Cat3;R40 Xn;R48/22	Carc.2 (H351) STOT RE.2 (H373) Repr.1B (H360D)	<10
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	Not Listed	*
Corn Starch	9005-25-8	232-679-6	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Flavor	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Povidone	9003-39-8	Not Listed	Not Listed	Not Listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	Not Listed	*
Hydroxypropyl cellulose	9004-64-2	Not Listed	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 R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE

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4. FIRST AID MEASURES

Eye Contact:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Contact:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation:	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure:	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions Aggravated by Exposure:	None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:	None
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5. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products:	Toxic or corrosive gases including oxides of carbon and oxides of sulfur
Fire / Explosion Hazards:	Not applicable

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

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7. HANDLING AND STORAGE

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Iron oxide

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
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

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

Hydrochlorothiazide

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Pfizer OEL TWA-8 Hr:	250µg/m ³
Titanium dioxide	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
ACGIH OELs - Notice of Intended Changes	Listed
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
Russia OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³
Sweden OEL - TWAs	5 mg/m ³
Switzerland OEL -TWAs	3 mg/m ³
Vietnam OEL - TWAs	6 mg/m ³
	5 mg/m ³
Calcium sulfate, dihydrate	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Germany (DFG) - MAK	1.5 mg/m ³
	4 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³
Switzerland OEL -TWAs	3 mg/m ³
Vietnam OEL - TWAs	6 mg/m ³
Spironolactone	
Pfizer OEL TWA-8 Hr:	90 µg/m ³ , Skin
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
Slovenia OEL - TWA	1000 mg/m ³
Switzerland OEL -TWAs	1000 ppm
Corn Starch	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Czech Republic OEL - TWA	4.0 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
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	4 mg/m ³
Spain OEL - TWA	10 mg/m ³
Switzerland OEL - TWAs	3 mg/m ³

Analytical Method:	Analytical method available for Spironolactone. Contact Pfizer Inc for further information.
Exposure Controls	
Engineering Controls:	General room ventilation is adequate unless the process generates dust, mist or fumes. Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection:	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Film-coated tablets	Color:	Tan
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	No data available		
pH:	No data available.		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available.		
Partition Coefficient: (Method, pH, Endpoint, Value)			
Povidone	No data available		
Magnesium stearate	No data available		
Corn Starch	No data available		
Hydroxypropyl cellulose	No data available		
Iron oxide			

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9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Titanium dioxide

No data available

Hydroxypropyl methylcellulose

No data available

Polyethylene glycol

No data available

Flavor

No data available

Calcium sulfate, dihydrate

No data available

Spironolactone

Predicted 7.4 Log D 3.12

Hydrochlorothiazide

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Short Term: Antihypertensive drug: has blood pressure-lowering properties

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on blood, kidneys, reproductive system.

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11. TOXICOLOGICAL INFORMATION

Known Clinical Effects: Signs and symptoms might include nausea, vomiting, cramps, dizziness, headache, vertigo, low blood pressure on standing, rash, urticaria, photosensitivity, electrolyte imbalance, muscle spasm, weakness, and restlessness. Hypersensitivity reactions may also occur in susceptible individuals. Effects on blood and blood-forming organs have also occurred. May cause adverse effects on the developing fetus.

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

Povidone

Rat Oral LD50 100 g/kg

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

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11. TOXICOLOGICAL INFORMATION

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))

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)	<i>Salmonella</i> , <i>E. coli</i>	Negative
Mammalian Cell Mutagenicity		Negative without activation

Hydrochlorothiazide

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vitro</i> Sister Chromatid Exchange	Chinese Hamster Ovary (CHO) cells	Positive
<i>In Vitro</i> Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
Dominant Lethal Assay	<i>Drosophila</i>	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)

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11. TOXICOLOGICAL INFORMATION

Iron oxide IARC:	Group 3 (Not Classifiable)
Titanium dioxide IARC:	Group 2B (Possibly Carcinogenic to Humans)
Spironolactone IARC:	Group 3 (Not Classifiable)
Hydrochlorothiazide IARC:	Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview:	Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.
Toxicity:	No data available
Persistence and Degradability:	No data available
Bio-accumulative Potential: Partition Coefficient: (Method, pH, Endpoint, Value) Spironolactone Predicted 7.4 Log D 3.12	
Mobility in Soil:	No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.
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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:

Class D, Division 2, Subdivision A



Iron oxide

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

Flavor

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

Povidone

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

Magnesium stearate

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

Hydroxypropyl methylcellulose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	Not Listed

Hydrochlorothiazide

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15. REGULATORY INFORMATION

<p>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</p>	<p>Not Listed Not Listed Present Present Schedule 4 200-403-3</p>
<p>Hydroxypropyl cellulose CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS/ELINCS List</p>	<p>Not Listed Not Listed Present Present Not Listed</p>
<p>Titanium dioxide CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS/ELINCS List</p>	<p>Not Listed carcinogen initial date 9/2/11 airborne, unbound particles of respirable size Present Present 236-675-5</p>
<p>Calcium sulfate, dihydrate CERCLA/SARA 313 Emission reporting California Proposition 65 Australia (AICS): EU EINECS/ELINCS List</p>	<p>Not Listed Not Listed Present Not Listed</p>
<p>Spironolactone 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</p>	<p>Not Listed carcinogen initial date 5/1/97 Present Present Schedule 4 200-133-6</p>
<p>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</p>	<p>Not Listed Not Listed Present Present Schedule 3 Not Listed</p>
<p>Corn Starch CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS):</p>	<p>Not Listed Not Listed Present Present</p>

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15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.1B; H360D - May damage the unborn child
Carcinogenicity-Cat.2; H351 - Suspected of causing cancer
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure

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

R40 - Limited evidence of a carcinogenic effect
R61 - May cause harm to the unborn child.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

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

Reasons for Revision: Updated Section 7 - Handling and Storage. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 12 - Ecological Information. Updated Section 11 - Toxicology Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information.

Revision date: 04-Mar-2015
Product Stewardship Hazard Communication

Prepared by: 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