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

Product Identifier
   Material Name: Spironolactone Tablets
      Trade Name: ALDACTONE; ALDACTONE-A; PRACTON; SPIRONOLACTONE-PFIZER
      Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
   Intended Use: Pharmaceutical product for the treatment of high blood pressure (hypertension).

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture
   GHS - Classification
      Reproductive Toxicity: Category 1B
      Carcinogenicity: Category 2
      Specific target organ systemic toxicity (repeated exposure): Category 2

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

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

Label Elements
   Signal Word: Danger
   Hazard Statements:
      H351 - Suspected of causing cancer
      H373 - May cause damage to organs through prolonged or repeated exposure
      H360D - May damage the unborn child
Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P314 - Get medical attention/advice if you feel unwell
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards
Australian Hazard Classification (NOHSC):

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maize starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
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<td>Not Listed</td>
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<tr>
<td>Magnesium stearate</td>
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<td>209-150-3</td>
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<tr>
<td>Calcium sulfate, dihydrate</td>
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<td>52-01-7</td>
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<td></td>
<td></td>
<td>Carc.Cat3;R40</td>
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<td>Xn;R48/22</td>
<td>Repr.1B (H360D)</td>
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<table>
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<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
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<td>Not Listed</td>
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<td>Not Listed</td>
<td>Not Listed</td>
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</table>

Additional Information:
* 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

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

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:
Emits oxides of sulfur under combustion.

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
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.

Maize starch

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Czech Republic OEL - TWA 4.0 mg/m³
Greece OEL - TWA 10 mg/m³
                       5 mg/m³
Ireland OEL - TWAs 10 mg/m³
                       4 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Slovakia OEL - TWA 4 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL -TWAs 3 mg/m³

Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Calcium sulfate, dihydrate

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Germany (DFG) - MAK 1.5 mg/m³
                       4 mg/m³
Portugal OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL -TWAs 3 mg/m³
Vietnam OEL - TWAs 6 mg/m³

Spironolactone

Pfizer OEL TWA-8 Hr: 90 µg/m³; Skin

Polyethylene glycol

Austria OEL - MAKs 1000 mg/m³
Germany - TRGS 900 - TWAs 1000 mg/m³
Germany (DFG) - MAK 1000 mg/m³ average molecular weight 200-600
Slovakia OEL - TWA 1000 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Tablet</td>
</tr>
<tr>
<td>Odor</td>
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</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
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</tr>
<tr>
<td>Water Solubility</td>
<td>No data available.</td>
</tr>
<tr>
<td>pH</td>
<td>No data available.</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C)</td>
<td>No data available.</td>
</tr>
<tr>
<td>Boiling Point (°C)</td>
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<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
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<tr>
<td>Spironolactone</td>
<td>Predicted 7.4  Log D 3.12</td>
</tr>
<tr>
<td>Povidone</td>
<td>No data available.</td>
</tr>
<tr>
<td>Maize starch</td>
<td>No data available.</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>No data available.</td>
</tr>
<tr>
<td>Peppermint flavor</td>
<td>No data available.</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>No data available.</td>
</tr>
<tr>
<td>Calcium sulfate, dihydrate</td>
<td>No data available.</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>No data available.</td>
</tr>
<tr>
<td>Decomposition Temperature (°C):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s)</td>
<td>No data available.</td>
</tr>
<tr>
<td>Vapor Pressure (kPa)</td>
<td>No data available.</td>
</tr>
<tr>
<td>Vapor Density (g/ml)</td>
<td>No data available.</td>
</tr>
<tr>
<td>Relative Density</td>
<td>No data available.</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available.</td>
</tr>
</tbody>
</table>
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: None known
- 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 be absorbed through the skin and cause systemic effects. Antihypertensive drug: has blood pressure-lowering properties
Known Clinical Effects: Adverse effects seen in clinical use include gastrointestinal discomfort, dizziness, and headache. Hypersensitivity reactions may also occur in susceptible individuals. Effects on blood and blood-forming organs have also occurred.

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

- Spironolactone
  - Rat Oral LD50 4121 mg/kg
  - Mouse Oral LD50 >1000mg/kg
  - Rabbit Oral LD50 >1000mg/kg
  - Rat Intraperitoneal LD50 786mg/kg
- Povidone
  - Rat Oral LD50 100 g/kg
- Magnesium stearate
  - Rat Oral LD50 > 2000 mg/kg
  - Rat Inhalation LC50 > 2000 mg/m³
- 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)

- Spironolactone
  - Skin Sensitization - GPMT Guinea Pig No effect
11. TOXICOLOGICAL INFORMATION

Polyethylene glycol
Eye Irritation   Rabbit   Mild
Skin Irritation   Rabbit   Mild

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spironolactone</td>
<td>13 Week(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>50 mg/kg</td>
<td>LOAEL</td>
<td>Blood</td>
</tr>
<tr>
<td></td>
<td>78 Week(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>50 mg/kg/day</td>
<td>LOAEL</td>
<td>Liver, Male reproductive system</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spironolactone</td>
<td>Reproductive &amp; Fertility</td>
<td>Rat</td>
<td>Oral</td>
<td>15 mg/kg/day</td>
<td>NOAEL</td>
<td>Fetotoxicity</td>
</tr>
<tr>
<td></td>
<td>Reproductive &amp; Fertility</td>
<td>Rat</td>
<td>Intraperitoneal</td>
<td>100 mg/kg/day</td>
<td>LOAEL</td>
<td>Fertility</td>
</tr>
<tr>
<td></td>
<td>Embryo / Fetal Development</td>
<td>Mouse</td>
<td>Intraperitoneal</td>
<td>100 mg/kg/day</td>
<td>LOAEL</td>
<td>Maternal Toxicity</td>
</tr>
<tr>
<td></td>
<td>Embryo / Fetal Development</td>
<td>Rat</td>
<td>Oral</td>
<td>50 mg/kg/day</td>
<td>LOAEL</td>
<td>Fetotoxicity</td>
</tr>
<tr>
<td></td>
<td>Embryo / Fetal Development</td>
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<td>20 mg/kg/day</td>
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<td>Fetotoxicity</td>
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</table>

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Study Type</th>
<th>Cell Type/Organism</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spironolactone</td>
<td>Bacterial Mutagenicity (Ames)</td>
<td>Salmonella, E. coli</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>Mammalian Cell Mutagenicity</td>
<td>Negative without activation</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spironolactone</td>
<td>104 Week(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>10 mg/kg/day</td>
<td>LOAEL</td>
<td>Benign tumors</td>
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<tr>
<td></td>
<td>52 Week(s)</td>
<td>Non-human Primate</td>
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<td>20 mg/kg/day</td>
<td>LOAEL</td>
<td>Reproductive System</td>
</tr>
</tbody>
</table>

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Spironolactone
IARC: Group 3 (Not Classifiable)

Povidone
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential:

ALDACTONE UNCOATED
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

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

Maize starch
CERCLA/SARA 313 Emission reporting  Not Listed
California Proposition 65  Not Listed
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  232-679-6
15. REGULATORY INFORMATION

Povidone

<table>
<thead>
<tr>
<th>Material</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
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<th>EU EINECS/ELINCS List</th>
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Peppermint flavor

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<tr>
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<th>Inventory - United States TSCA - Sect. 8(b)</th>
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Magnesium stearate

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<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
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<td>Not Listed</td>
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<td>Present</td>
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Hydroxypropyl methylcellulose

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<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>Standard for the Uniform Scheduling for Drugs and Poisons:</th>
<th>EU EINECS/ELINCS List</th>
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Calcium sulfate, dihydrate

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<th>California Proposition 65</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
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<td>Not Listed</td>
<td>Present</td>
<td>Not Listed</td>
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Spironolactone

<table>
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<tr>
<th>Material</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>Standard for the Uniform Scheduling for Drugs and Poisons:</th>
<th>EU EINECS/ELINCS List</th>
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<tbody>
<tr>
<td></td>
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<td></td>
<td>Present</td>
<td>Present</td>
<td>Schedule 4</td>
<td>200-133-6</td>
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Polyethylene glycol

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<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
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</thead>
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<td>Not Listed</td>
<td>Not Listed</td>
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15. REGULATORY INFORMATION

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<th>Schedule 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

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

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
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child

Carcinogenic: Category 3
Xn - Harmful
Toxic to Reproduction: Category 2
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 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 16 - Other Information.

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Prepared by: Product Stewardship Hazard Communication

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End of Safety Data Sheet