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

Product Identifier

Material Name: Ramipril Capsules

Trade Name: ALTACE

Synonyms: Ramipril Capsules

Chemical Family: Not determined

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

Intended Use: Pharmaceutical product used as Antihypertensive

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 2

Label Elements

Signal Word: Warning

Hazard Statements: H361d - Suspected of damaging the unborn child

Precautionary Statements:

P201 - Obtain special instructions before use

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
Other Hazards

An Occupational Exposure Value has been established for this substance (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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

<table>
<thead>
<tr>
<th>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch, pregelatinized</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</td>
<td>&lt;0.1</td>
<td></td>
</tr>
<tr>
<td>Ramipril</td>
<td>87333-19-5</td>
<td>Not Listed</td>
<td>Repr. 2 (H361d)</td>
<td>&lt;10</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hard gelatin capsules</td>
<td>MIXTURE</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Gelatin</td>
<td>9000-70-8</td>
<td>232-554-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. * Proprietary
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.

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: Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride, and other chlorine-containing compounds.

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

Advice for Fire-Fighters
During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Additional Information: Dust is combustible when suspended in air. Control ignition sources in areas where this material is present.

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. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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 at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

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.

Starch, pregelatinized

<table>
<thead>
<tr>
<th>Threshold Limit Value (TWA)</th>
<th>10 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td></td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>
EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Controls

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:

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 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 gloves (e.g. Nitrile, etc.) are 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.)
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Hard-gelatin Capsule
Odor: No data available.
Molecular Formula: 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)
Gelatin
No data available
Ramipril
No data available
Hard gelatin capsules
No data available
Starch, pregelatinized
No data available
Titanium dioxide
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
Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
10. STABILITY AND REACTIVITY

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electrostatic discharge).

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: Accidental ingestion may cause effects similar to those seen in clinical use. In humans, the use of drugs in this class (ACE inhibitors) can cause fetal and neonatal toxicity, including low blood pressure and kidney failure, when they are taken during pregnancy.

Known Clinical Effects: Effects reported during clinical use include dizziness, headache, lethargy, changes in blood pressure, nausea, and abdominal pain. Additionally, red, itchy, flaky skin (dermatitis), swelling of skin, mucosa, and submucosal tissues (angioneurotic edema), cough, increased potassium, may occur.

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ramipril</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 10 g/kg</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 7500 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>LD50</td>
<td>50 mg/kg</td>
</tr>
</tbody>
</table>

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.

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>Ramipril</td>
<td>Reproductive</td>
<td>Rat</td>
<td>Oral</td>
<td>500 mg/kg/day</td>
<td>NOAEL</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>Fertility</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Embryo / Fetal</td>
<td>Rat</td>
<td>Oral</td>
<td>400 times human</td>
<td>NOAEL</td>
<td>Not Teratogenic</td>
</tr>
<tr>
<td></td>
<td>Development</td>
<td></td>
<td></td>
<td>dose</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Embryo / Fetal</td>
<td>Monkey</td>
<td>Oral</td>
<td>400 times human</td>
<td>NOAEL</td>
<td>Not Teratogenic</td>
</tr>
<tr>
<td></td>
<td>Development</td>
<td>Rabbit</td>
<td>Oral</td>
<td>2 times human</td>
<td>NOAEL</td>
<td>Not Teratogenic</td>
</tr>
</tbody>
</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>Ramipril</td>
<td>Bacterial Mutagenicity (Ames)</td>
<td>Salmonella, E. coli</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>Micronucleus</td>
<td>Mouse</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>Unscheduled DNA Synthesis</td>
<td>Human</td>
<td>Negative</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>Ramipril</td>
<td>24 Month(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>500 mg/kg/day</td>
<td>NOAEL</td>
<td>Not carcinogenic</td>
</tr>
<tr>
<td></td>
<td>18 Month(s)</td>
<td>Mouse</td>
<td>Oral</td>
<td>1000 mg/kg/day</td>
<td>NOAEL</td>
<td>Not carcinogenic</td>
</tr>
</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

Carcinogen Status: None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

Titanium dioxide
IARC: Group 2B (Possibly Carcinogenic to Humans)

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

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
15. REGULATORY INFORMATION

Hard gelatin capsules
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

Starch, pregelatinized
- 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:
  - EU EINECS/ELINCS List: 232-679-6

Gelatin
- 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: 232-554-6

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
- EU EINECS/ELINCS List: 236-675-5

Ramipril
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Standard for the Uniform Scheduling for Drugs and Poisons:
  - Schedule 4
- EU EINECS/ELINCS List: Not Listed

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3
Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child

Data Sources: Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

Revision date: 15-Nov-2018

Prepared by: Product Stewardship Hazard Communication

Pfizer Global Environment, Health, and Safety Operations
Pfizer Inc believes that the information contained in this 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