

MATERIAL SAFETY DATA SHEET

Revision date: 06-Dec-2012

Version: 1.0

Page 1 of 7

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

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

Material Name: Altace Capsules

| | |
|-------------------------|-------------------------------------------------|
| Trade Name: | ALTACE |
| Synonyms: | Ramipril Capsules |
| Chemical Family: | Not determined |
| Intended Use: | Pharmaceutical product used as Antihypertensive |

2. HAZARDS IDENTIFICATION

Appearance: Yellow, orange, red, or blue hard gelatin capsules
Signal Word: WARNING

Statement of Hazard: Suspected of damaging the unborn child.

Additional Hazard Information:
Short Term:

Antihypertensive drug: has blood pressure-lowering properties
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.
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.

Known Clinical Effects:

EU Indication of danger: Toxic to Reproduction: Category 3

EU Hazard Symbols:
Xn



EU Risk Phrases:

Australian Hazard Classification (NOHSC):

R63 - Possible risk of harm to the unborn child.
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 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.

MATERIAL SAFETY DATA SHEET

Material Name: Altace Capsules
Revision date: 06-Dec-2012

Page 2 of 7
Version: 1.0

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | % |
|------------------------|------------|-----------------------|-------------------|------|
| Starch, pregelatinized | 9005-25-8 | 232-679-6 | Not Listed | * |
| Ramipril | 87333-19-5 | Not Listed | Repr.Cat.3;R63 | <10 |
| Titanium dioxide | 13463-67-7 | 236-675-5 | Not Listed | <0.1 |

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | % |
|-----------------------|------------|-----------------------|-------------------|---|
| Gelatin | 9000-70-8 | 232-554-6 | Not Listed | * |
| Hard gelatin capsules | MIXTURE | Not Listed | Not Listed | * |

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

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.

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

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

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

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

6. ACCIDENTAL RELEASE MEASURES

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

MATERIAL SAFETY DATA SHEET

Material Name: Altace Capsules
Revision date: 06-Dec-2012

Page 3 of 7
Version: 1.0

| | |
|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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: | 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. |
| 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.

Starch, pregelatinized

| | |
|-----------------------------------|------------------------|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m ³ |
| 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 |
| Ireland OEL - TWAs | 5 mg/m ³ |
| | 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 |

Ramipril

| | |
|----------------------|---------------------|
| Pfizer OEL TWA-8 Hr: | 25µg/m ³ |
|----------------------|---------------------|

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 |

MATERIAL SAFETY DATA SHEET

Material Name: Altace Capsules
Revision date: 06-Dec-2012

Page 4 of 7
Version: 1.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|---------------------------|------------------------|
| 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 |
| Spain OEL - TWA | 10 mg/m ³ |
| Sweden OEL - TWAs | 5 mg/m ³ |

| | |
|-----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Analytical Method: | Analytical method available. 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. |
| Environmental Exposure Controls: | Refer to specific Member State legislation for requirements under Community environmental legislation. |
| 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: | Hard-gelatin Capsule | Color: | Yellow, Orange Red, Blue |
| Molecular Formula: | Mixture | Molecular Weight: | Mixture |
| Partition Coefficient (Calculated; pH 7.4 - Log D): | 0.33 (ramipril) | | |
| Polymerization: | Will not occur | | |

10. STABILITY AND REACTIVITY

| | |
|--------------------------------|-------------------------------------------------------------------------------------------------------------|
| Chemical Stability: | Stable under normal conditions of use. |
| 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 |

MATERIAL SAFETY DATA SHEET

Material Name: Altace Capsules
Revision date: 06-Dec-2012

Page 5 of 7
Version: 1.0

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)

Ramipril

Rat Oral LD50 > 10 g/kg

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg

Rat Subcutaneous LD 50 50 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.

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

Ramipril

Reproductive & Fertility Rat Oral 500 mg/kg/day NOAEL Negative

Embryo / Fetal Development Rat Oral 400 times human dose NOAEL Not Teratogenic

Embryo / Fetal Development Monkey Oral 400 times human dose NOAEL Not Teratogenic

Embryo / Fetal Development Rabbit Oral 2 times human dose NOAEL Not Teratogenic

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

Ramipril

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

Micronucleus Mouse Negative

Unscheduled DNA Synthesis Human Negative

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

Ramipril

24 Month(s) Rat Oral 500 mg/kg/day NOAEL Not carcinogenic

18 Month(s) Mouse Oral 1000 mg/kg/day NOAEL Not carcinogenic

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)

OSHA: Listed

12. ECOLOGICAL INFORMATION

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

**Partition Coefficient
(Calculated; pH 7.4 - Log D):** 0.33 (ramipril)

MATERIAL SAFETY DATA SHEET

Material Name: Altace Capsules
Revision date: 06-Dec-2012

Page 6 of 7
Version: 1.0

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

EU Symbol: Xn
EU Indication of danger: Toxic to Reproduction: Category 3

EU Risk Phrases:
R63 - Possible risk of harm to the unborn child.

EU Safety Phrases:
S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING
Suspected of damaging the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A
(Bad file name or number)

| | |
|-----------------------------------------------------------------|-----------|
| Starch, pregelatinized | |
| 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 |

Gelatin

MATERIAL SAFETY DATA SHEET

Material Name: Altace Capsules
Revision date: 06-Dec-2012

Page 7 of 7
Version: 1.0

15. REGULATORY INFORMATION

| | |
|---------------------------------------------|-----------|
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 232-554-6 |

Ramipril

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

Titanium dioxide

| | |
|---------------------------------------------|--------------------------------|
| California Proposition 65 | carcinogen initial date 9/2/11 |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 236-675-5 |

16. OTHER INFORMATION

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

R63 - Possible risk of harm to the unborn child.

Data Sources: Pfizer proprietary drug development information.

Prepared by: 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