



# SAFETY DATA SHEET

Revision date: 06-Mar-2015

Version: 2.0

Page 1 of 9

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

### Product Identifier

**Material Name:** Altace 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

### 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 2

#### EU Classification:

EU Indication of danger: Toxic to Reproduction: Category 3

#### EU Risk Phrases:

R63 - Possible risk of harm to the unborn child.

### 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

# SAFETY DATA SHEET

Material Name: Altace Capsules  
Revision date: 06-Mar-2015

Page 2 of 9  
Version: 2.0



## Other Hazards

Australian Hazard Classification (NOHSC):

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.

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

### Hazardous

| Ingredient             | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | %    |
|------------------------|------------|-----------------------|-------------------|--------------------|------|
| Starch, pregelatinized | 9005-25-8  | 232-679-6             | Not Listed        | Not Listed         | *    |
| Titanium dioxide       | 13463-67-7 | 236-675-5             | Not Listed        | Not Listed         | <0.1 |
| Ramipril               | 87333-19-5 | Not Listed            | Repr.Cat.3;R63    | Repr. 2 (H361d)    | <10  |

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

**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 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

## SAFETY DATA SHEET

Material Name: Altace Capsules  
Revision date: 06-Mar-2015

Page 3 of 9  
Version: 2.0

**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 fire fighting 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. Clean up 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

## SAFETY DATA SHEET

Material Name: Altace Capsules  
Revision date: 06-Mar-2015

Page 4 of 9  
Version: 2.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Starch, pregelatinized

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

#### Titanium dioxide

|   |                        |
|---|------------------------|
| ACGIH Threshold Limit Value (TWA)       | 10 mg/m <sup>3</sup>   |
| ACGIH OELs - Notice of Intended Changes | Listed                 |
| Australia TWA                           | 10 mg/m <sup>3</sup>   |
| Austria OEL - MAKs                      | 5 mg/m <sup>3</sup>    |
| Belgium OEL - TWA                       | 10 mg/m <sup>3</sup>   |
| Bulgaria OEL - TWA                      | 10.0 mg/m <sup>3</sup> |
| Denmark OEL - TWA                       | 6 mg/m <sup>3</sup>    |
| Estonia OEL - TWA                       | 5 mg/m <sup>3</sup>    |
| France OEL - TWA                        | 10 mg/m <sup>3</sup>   |
| Greece OEL - TWA                        | 10 mg/m <sup>3</sup>   |
|   | 5 mg/m <sup>3</sup>    |
| Ireland OEL - TWAs                      | 10 mg/m <sup>3</sup>   |
|   | 4 mg/m <sup>3</sup>    |
| Latvia OEL - TWA                        | 10 mg/m <sup>3</sup>   |
| Lithuania OEL - TWA                     | 5 mg/m <sup>3</sup>    |
| OSHA - Final PELs - TWAs:               | 15 mg/m <sup>3</sup>   |
| Poland OEL - TWA                        | 10.0 mg/m <sup>3</sup> |
| Portugal OEL - TWA                      | 10 mg/m <sup>3</sup>   |
| Romania OEL - TWA                       | 10 mg/m <sup>3</sup>   |
| Russia OEL - TWA                        | 10 mg/m <sup>3</sup>   |
| Spain OEL - TWA                         | 10 mg/m <sup>3</sup>   |
| Sweden OEL - TWAs                       | 5 mg/m <sup>3</sup>    |
| Switzerland OEL - TWAs                  | 3 mg/m <sup>3</sup>    |
| Vietnam OEL - TWAs                      | 6 mg/m <sup>3</sup>    |
|   | 5 mg/m <sup>3</sup>    |

#### Ramipril

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

#### Analytical Method: Exposure Controls

Analytical method available. Contact Pfizer Inc for further information.

## SAFETY DATA SHEET

Material Name: Altace Capsules  
Revision date: 06-Mar-2015

Page 5 of 9  
Version: 2.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

|                                       |  |
|---------------------------------------|--|
| <b>Engineering Controls:</b>          | 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. |
| <b>Personal Protective Equipment:</b> | Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).  |
| <b>Hands:</b>                         | Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.  |
| <b>Eyes:</b>                          | Wear safety glasses or goggles if eye contact is possible.   |
| <b>Skin:</b>                          | Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.  |
| <b>Respiratory protection:</b>        | 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

|   |                      |                          |                          |
|---|----------------------|--------------------------|--------------------------|
| <b>Physical State:</b>                                      | Hard-gelatin Capsule | <b>Color:</b>            | Yellow, Orange Red, Blue |
| <b>Odor:</b>  | No data available.   | <b>Odor Threshold:</b>   | No data available.       |
| <b>Molecular Formula:</b>                                   | Mixture              | <b>Molecular Weight:</b> | Mixture                  |
| <b>Solvent Solubility:</b>                                  | No data available    |                          |                          |
| <b>Water Solubility:</b>                                    | No data available    |                          |                          |
| <b>pH:</b>  | No data available.   |                          |                          |
| <b>Melting/Freezing Point (°C):</b>                         | No data available    |                          |                          |
| <b>Boiling Point (°C):</b>                                  | No data available.   |                          |                          |
| <b>Partition Coefficient: (Method, pH, Endpoint, Value)</b> |                      |                          |                          |
| <b>Gelatin</b>  |                      |                          |                          |
| No data available   |                      |                          |                          |
| <b>Ramipril</b>   |                      |                          |                          |
| No data available   |                      |                          |                          |
| <b>Hard gelatin capsules</b>                                |                      |                          |                          |
| No data available   |                      |                          |                          |
| <b>Starch, pregelatinized</b>                               |                      |                          |                          |
| No data available   |                      |                          |                          |
| <b>Titanium dioxide</b>                                     |                      |                          |                          |
| No data available   |                      |                          |                          |
| <b>Decomposition Temperature (°C):</b>                      | No data available.   |                          |                          |
| <b>Evaporation Rate (Gram/s):</b>                           | No data available    |                          |                          |
| <b>Vapor Pressure (kPa):</b>                                | No data available    |                          |                          |
| <b>Vapor Density (g/ml):</b>                                | No data available    |                          |                          |
| <b>Relative Density:</b>                                    | No data available    |                          |                          |
| <b>Viscosity:</b>   | No data available    |                          |                          |
| <b>Flammability:</b>  |                      |                          |                          |
| <b>Autoignition Temperature (Solid) (°C):</b>               | No data available    |                          |                          |
| <b>Flammability (Solids):</b>                               | No data available    |                          |                          |
| <b>Flash Point (Liquid) (°C):</b>                           | No data available    |                          |                          |
| <b>Upper Explosive Limits (Liquid) (% by Vol.):</b>         | No data available    |                          |                          |
| <b>Lower Explosive Limits (Liquid) (% by Vol.):</b>         | No data available    |                          |                          |
| <b>Polymerization:</b>                                      | Will not occur       |                          |                          |

## SAFETY DATA SHEET

Material Name: Altace Capsules  
Revision date: 06-Mar-2015

Page 6 of 9  
Version: 2.0

### 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:** 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:** 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.  
**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)

##### Ramipril

Rat Oral LD50 > 10 g/kg

##### Titanium dioxide

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

## SAFETY DATA SHEET

Material Name: Altace Capsules  
Revision date: 06-Mar-2015

Page 7 of 9  
Version: 2.0

### 11. TOXICOLOGICAL INFORMATION

#### 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)

### 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

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**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

# SAFETY DATA SHEET

Material Name: Altace Capsules  
Revision date: 06-Mar-2015

Page 8 of 9  
Version: 2.0

## 15. REGULATORY INFORMATION

### Canada - WHMIS: Classifications

#### WHMIS hazard class:

Class D, Division 2, Subdivision A



#### 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: | Present    |
| 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  |

#### Hard gelatin capsules

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

#### Titanium dioxide

|   |   |
|---|---|
| CERCLA/SARA 313 Emission reporting          | Not Listed  |
| California Proposition 65                   | carcinogen initial date 9/2/11 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                                  | developmental toxicity initial date 10/1/92 |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 4                                  |
| EU EINECS/ELINCS List                                      | Not Listed                                  |

## 16. OTHER INFORMATION

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



## SAFETY DATA SHEET

**Material Name:** Altace Capsules  
**Revision date:** 06-Mar-2015

**Page 9 of 9**  
**Version: 2.0**

---

Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child

Toxic to Reproduction: Category 3

R63 - Possible risk of harm to the unborn child.

**Data Sources:** Pfizer proprietary drug development information.

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 7 - Handling and Storage. Updated Section 16 - Other Information.

**Revision date:** 06-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**