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

Product Identifier
Material Name: Crizotinib Capsules
Trade Name: XALKORI, CRIZALK
Chemical Family: Anaplastic Lymphoma Kinase Inhibitor

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
Intended Use: Pharmaceutical product for the treatment of lung cancer

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
Serious Eye Damage/Eye Irritation: Category 1
Skin Sensitization: Category 1
Germ Cell Mutagenicity: Category 2
Acute aquatic toxicity: Category 1

Label Elements
Signal Word: Danger
Hazard Statements: H318 - Causes serious eye damage
H317 - May cause an allergic skin reaction
H341 - Suspected of causing genetic defects
H400 - Very toxic to aquatic life

PZ01417
Precautionary Statements:

P280 - Wear protective gloves/protective clothing/eye protection/face protection
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTRE or doctor/physician
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P272 - Contaminated work clothing must not be allowed out of the workplace
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P321 - Specific treatment (see supplemental instructions on the administration of antidotes on this label)
P363 - Wash contaminated clothing before reuse
P202 - Do not handle until all safety precautions have been read and understood
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P273 - Avoid release to the environment
P391 - Collect spillage
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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>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></td>
<td>Crizotinib</td>
<td>877399-52-5</td>
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<td>Eye Dam.1 (H318) Skin Sens.1 (H317) Muta. 2 (H341) Aquatic Acute 1 (H400)</td>
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<td>Dicalcium Phosphate</td>
<td>7757-93-9</td>
<td>231-826-1</td>
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<tr>
<td></td>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
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<tr>
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<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
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<tr>
<td></td>
<td>Ferric oxide red</td>
<td>1309-37-1</td>
<td>215-168-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td></td>
<td>Sodium starch glycolate</td>
<td>9063-38-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
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:**
Formation of toxic gases is possible during heating or fire.

**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.

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
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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

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.

Crizotinib
Pfizer OEL TWA-8 Hr: 15µg/m³, Sensitizer, Severe Eye Irritant

Dicalcium Phosphate
Latvia OEL - TWA 10 mg/m³

Microcrystalline cellulose
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
Switzerland OEL -TWAs 4 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³
Sweden OEL - TWAs 3 mg/m³

Magnesium stearate
Lithuania OEL - TWA 5 mg/m³

Ferric oxide red

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**SAFETY DATA SHEET**

**Material Name:** Crizotinib Capsules

**Revision date:** 08-Feb-2018

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Material</th>
<th>Threshold Limit Value (TWA)</th>
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<tbody>
<tr>
<td>ACGIH</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
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<tr>
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<td>France OEL - TWA</td>
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#### Titanium dioxide

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<td>10.0 mg/m³</td>
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<td>Denmark OEL - TWA</td>
<td>6 mg/m³</td>
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<td>Estonia OEL - TWA</td>
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<td>France OEL - TWA</td>
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<tr>
<td>Greece OEL - TWA</td>
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<td></td>
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<tr>
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<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>4 mg/m³</td>
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<tr>
<td>Latvia OEL - TWA</td>
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<td>Lithuania OEL - TWA</td>
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<tr>
<td>OSHA - Final PELS - TWAs</td>
<td>15 mg/m³</td>
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<td>Poland OEL - TWA</td>
<td>10.0 mg/m³</td>
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<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
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<td>Romania OEL - TWA</td>
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<td>Sweden OEL - TWAs</td>
<td>5 mg/m³</td>
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<tr>
<td>Switzerland OEL - TWAs</td>
<td>3 mg/m³</td>
</tr>
</tbody>
</table>
8. 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.)

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

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Capsule</th>
<th>Color:</th>
<th>White / Pink and Pink / Pink</th>
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<tbody>
<tr>
<td>Odor:</td>
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<td>Odor Threshold:</td>
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<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

| 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) | Predicted 7.4 Log D 2.07 |
| Crizotinib | |
| Dicalcium Phosphate | No data available |
| Microcrystalline cellulose | No data available |
| Silicium dioxide | No data available |
| Sodium starch glycolate | No data available |
| Magnesium stearate | |

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9. PHYSICAL AND CHEMICAL PROPERTIES

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.

Known Clinical Effects: Based on clinical trials in humans, possible adverse effects following exposure to this compound may include: diarrhea, nausea, vomiting, fatigue, visual disturbances, and headache. Additionally, effects on liver, respiratory system, cardiovascular system may occur.

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

Microcrystalline cellulose
- Rat Oral LD50 > 5000 mg/kg
- Rabbit Dermal LD50 > 2000 mg/kg

Magnesium stearate
- Rat Oral LD50 > 2000 mg/kg
- Rat Inhalation LC50 > 2000 mg/m³
11. TOXICOLOGICAL INFORMATION

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.

Irritation / Sensitization: (Study Type, Species, Severity)

Crizotinib
- Skin Corrosivity (In vitro, RHE) Not applicable Negative
- Eye Irritation (In vitro, BCOP) Not applicable Negative
- Skin Sensitization - LLNA Mouse Positive

Microcrystalline cellulose
- Skin Irritation Rabbit Non-irritating
- Eye Irritation Rabbit Non-irritating

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

Crizotinib
- 7 Day(s) Rat Oral 150 mg/kg/day NOAEL None identified
- 28 Day(s) Mouse Oral 200 mg/kg/day NOAEL None identified
- 1 Month(s) Rat Oral 10 mg/kg/day NOAEL Bone Marrow, Kidney, Male reproductive system
- 1 Month(s) Dog Oral 20 mg/kg/day NOAEL None identified
- 3 Month(s) Rat Oral (M) 100 / (F) 250 mg/kg/day LOAEL Male reproductive system, Bone Marrow, Liver, Gastrointestinal system, Pituitary
- 3 Month(s) Dog Oral 25 mg/kg/day NOAEL Blood

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Crizotinib
- Embryo / Fetal Development Rat Oral 200 mg/kg/day LOAEL Maternal toxicity, Developmental toxicity
- Embryo / Fetal Development Rabbit Oral 60 mg/kg/day NOAEL Maternal Toxicity
- Embryo / Fetal Development Rabbit Oral 60 mg/kg/day LOAEL Developmental toxicity

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

Crizotinib
- Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative
- In Vitro Micronucleus Chinese Hamster Ovary (CHO) cells Positive without activation
- In Vitro Chromosome Aberration Human Lymphocytes Positive
- In Vivo Micronucleus Rat Bone Marrow Positive

Carcinogen Status: See below

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

Ferric oxide red
- IARC: Group 3 (Not Classifiable)
11. TOXICOLOGICAL INFORMATION

12. ECOLOGICAL INFORMATION

Environmental Overview: Very toxic to aquatic organisms. Releases to the environment should be avoided.

Toxicity:
Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Crizotinib
*Cyprinodon variegatus* (Sheepshead Minnow) OECD LC50 96 Hours > 5.2 mg/L
*Skeletonema costatum* (Marine Diatom) OECD EC50 72 Hours < 0.10-0.19 mg/L
*Tisbe battagliai* (Marine Copepod) OECD EC50 48 Hours 0.66 mg/L

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Crizotinib
Activated sludge OECD EC50 > 1000 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)

Crizotinib
Predicted 7.4 Log D 2.07

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.

This material is regulated for transportation as a hazardous material/dangerous good.

UN number: UN 3077
UN proper shipping name: Environmentally Hazardous Substance, Solid, n.o.s (crizotinib)
Transport hazard class(es): 9
Packing group: III
SAFETY DATA SHEET

5 kg/5L Exception:
UN3082 and UN3077 materials contained in good quality packaging in the quantities listed below are not regulated as dangerous goods for transport by any mode:

* Single packagings containing a net quantity of 5 liters or less for liquids or a net mass of 5 kg or less for solids.
* Combination packagings containing a net quantity per inner packaging of 5 liters or less for liquids or a net mass of 5 kg or less for solids.

IMDG
Environmental Hazard(s): Marine Pollutant

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Crizotinib
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

Dicalcium Phosphate
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 231-826-1

Microcrystalline cellulose
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 232-674-9

Sodium starch glycolate
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
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
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<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gelatin</td>
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<td>CERCLA/SARA 313 Emission reporting</td>
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<tr>
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<td>Australia (AICS):</td>
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<td>EU EINECS/ELINCS List</td>
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</table>

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

| Ferric oxide red                    |
| 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              |

| Titanium dioxide                    |
| 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              | 236-675-5              |

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

- Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage
- Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction
- Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects
- Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 14 - Transport Information.

Revision date: 08-Feb-2018

Prepared by: Product Stewardship Hazard Communication

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