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

Product Identifier

Material Name: Axitinib Film Coated Tablets
Trade Name: INLYTA
Chemical Family: Not determined

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

Intended Use: Pharmaceutical product used as antineoplastic

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Germ Cell Mutagenicity: Category 2
Reproductive Toxicity: Category 2
Specific target organ systemic toxicity (repeated exposure): Category 2

Label Elements

Signal Word: Warning
Hazard Statements:
H373 - May cause damage to organs through prolonged or repeated exposure
H341 - Suspected of causing genetic defects
H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.

Precautionary Statements:
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P314 - Get medical attention/advice if you feel unwell
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
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>
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<tr>
<td>Axitinib</td>
<td>319460-85-0</td>
<td>Not Listed</td>
<td>Muta. 2 (H341)</td>
<td>Repr. 2 (H361fd) STOT RE 2 (H373) Aquatic Acute 1 (H400)</td>
<td>&lt;5</td>
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<tr>
<td>Magnesium Stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td></td>
<td>*</td>
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</tbody>
</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 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.
**SAFETY DATA SHEET**

Material Name: Axitinib Film Coated Tablets

Revision date: 07-Feb-2018

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**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

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**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.

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**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.

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**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 product used as antineoplastic.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Axitinib
Pfizer OEL TWA-8 Hr: 10µg/m³

Magnesium Stearate
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

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 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: Tablets
Odor: No data available.
Color: Red
Molecular Formula: Mixture
Odor Threshold: No data available.
Molecular Weight: 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)
Axitinib
Predicted 7.4 Log D 3.83
Cellulose microcrystalline
No data available
Croskarmellose sodium
No data available
Lactose NF, monohydrate

PZ01419
9. PHYSICAL AND CHEMICAL PROPERTIES
No data available

Opadry II Red
No data available

Magnesium Stearate
No data available

Water, purified
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: increase in blood pressure (hypertension), diarrhea, fatigue, lack of appetite, nausea, vomiting, constipation, inflammation of the mouth (stomatitis), hand-foot syndrome.

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

Axitinib
Mouse Oral NOAEL 2000 mg/kg
Dog Oral NOAEL > 2000mg/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.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)
11. TOXICOLOGICAL INFORMATION

Axitinib
28 Day(s)  Mouse  Oral  10 mg/kg/day  NOAEL  Blood, Male reproductive system, Female reproductive system
28 Day(s)  Dog  Oral  10 mg/kg/day  LOAEL  Bone Marrow, Gastrointestinal system, Lymphatic system, Reproductive system
26 Week(s)  Mouse  Oral  10 mg/kg/day  LOAEL  Blood, Bone, Gastrointestinal system, Lymphatic system, Reproductive system
26 Week(s)  Dog  Oral  6 mg/kg/day  NOAEL  Gastrointestinal system, Lymphatic system
39 Week(s)  Dog  Oral  (F) 6 mg/kg/day (3 mg/kg BID)  NOAEL  None identified
39 Week(s)  Dog  Oral  (M) 3 mg/kg/day (1.5 mg/kg BID)  LOAEL  Male reproductive system

Magnesium Stearate
13 Week(s)  Rat  Oral  1092 g/kg  LOAEL  Liver

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

Axitinib
Embryo / Fetal Development  Mouse  Oral  3 mg/kg/day (1.5 mg/kg BID)  NOAEL  Maternal toxicity
Embryo / Fetal Development  Mouse  Oral  1 mg/kg/day (0.5 mg/kg BID)  NOAEL  Developmental toxicity, Teratogenic
Fertility & Early Embryonic Development - Males  Mouse  Oral  100 mg/kg/day (50 mg/kg BID)  NOAEL  Paternal toxicity
Fertility & Early Embryonic Development - Males  Mouse  Oral  10 mg/kg/day (5 mg/kg BID)  NOAEL  Reproductive toxicity
Fertility & Early Embryonic Development-Females  Mouse  Oral  250 mg/kg/day (125 mg/kg BID)  NOAEL  Maternal Toxicity
Fertility & Embryonic Development-Females  Mouse  Oral  < 30 mg/kg/day (15 mg/kg BID)  NOAEL  Reproductive toxicity

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

Axitinib
Bacterial Mutagenicity (Ames)  Salmonella, E. coli  Negative
In Vitro Cytogenetics  Human Lymphocytes  Negative
In Vivo Micronucleus  Mouse Bone Marrow  Positive

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

12. ECOLOGICAL INFORMATION

Environmental Overview:  This formulation has not been tested as a whole, the following apply to component substance(s): Releases to the environment should be avoided.

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

Axitinib
Skeletonema costatum (Marine Diatom)  OECD EbC50 72 Hours  > 0.043 mg/L
Mysidopsis bahia (Mysid Shrimp)  OPPTS LC50 96 Hours  > 0.063 mg/L
Cyprinodon variegatus (Sheepshead Minnow)  OPPTS LC50 96 Hours  > 0.055 mg/L
Pseudokirchneriella subcapitata (Green Alga)  OECD EC50 72 Hours  0.9 mg/L
Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Axitinib
Activated sludge OECD EC50 > 1000 mg/L

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Axitinib
Daphnia magna (Water Flea) OECD 21 Day(s) NOEC 0.088 mg/L
Pimephales promelas (Fathead Minnow) OECD 32 Day(s) NOEC 0.0035 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)
Axitinib
Predicted 7.4 Log D 3.83

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

Axitinib
CERCLA/SARA 313 Emission reporting Not Listed
### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>California Proposition 65</th>
<th>Standard for the Uniform Scheduling for Drugs and Poisons</th>
<th>EU EINECS/ELINCS List</th>
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<tbody>
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<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
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<tr>
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<table>
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<tr>
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<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>REACH - Annex IV - Exemptions from the obligations of Register:</th>
<th>EU EINECS/ELINCS List</th>
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</tr>
</tbody>
</table>

### 16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3
Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects
Reproductive toxicity-Cat.2; H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects

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

Reasons for Revision:
Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 2 - Hazard Identification. Updated Section 12 - Ecological Information.
Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 07-Feb-2018
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