



MATERIAL SAFETY DATA SHEET

Revision date: 11-Jan-2012

Version: 2.0

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: Axitinib Film Coated Tablets

Trade Name:	INLYTA
Chemical Family:	Not determined
Intended Use:	Pharmaceutical product

2. HAZARDS IDENTIFICATION

Appearance: Red tablet
Signal Word: WARNING

Statement of Hazard: Suspected of damaging fertility or the unborn child.
Suspected of causing genetic defects.

Additional Hazard Information:
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.

EU Indication of danger: Mutagenic: Category 3
Toxic to Reproduction: Category 3

EU Hazard Symbols:



EU Risk Phrases:

R62 - Possible risk of impaired fertility.
R63 - Possible risk of harm to the unborn child.
R68 - Possible risk of irreversible effects.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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: Axitinib Film Coated Tablets
Revision date: 11-Jan-2012

Page 2 of 7
Version: 2.0

2. HAZARDS IDENTIFICATION

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Axitinib	319460-85-0	Not Listed	Muta. Cat.3;R68 Repr. Cat.3;R62 Repr. Cat.3;R63 Xn;R48-22	5
Magnesium Stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Cellulose microcrystalline	9004-34-4	Not Listed	Not Listed	*
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	*
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	*
Opadry II Red	Not Assigned	Not Listed	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	*

Additional Information:

* Proprietary

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:	Formation of toxic gases is possible during heating or fire.
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.

MATERIAL SAFETY DATA SHEET

Material Name: Axitinib Film Coated Tablets
Revision date: 11-Jan-2012

Page 3 of 7
Version: 2.0

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
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:	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.
Storage Conditions:	Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Axitinib

Pfizer OEL TWA-8 Hr:	10µg/m ³
----------------------	---------------------

Magnesium Stearate

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

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.

MATERIAL SAFETY DATA SHEET

Material Name: Axitinib Film Coated Tablets
Revision date: 11-Jan-2012

Page 4 of 7
Version: 2.0

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Tablets
Molecular Formula: Mixture
Color: Red
Molecular Weight: Mixture

Partition Coefficient
(Measured - Log Pow/Log Kow): 2.01 (axitinib)

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
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

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)

Axitinib

Mouse Oral NOEL 2000 mg/kg
Dog Oral NOEL > 2000 mg/kg

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

Axitinib

28 Day(s) Mouse Oral 10 mg/kg/day NOEL 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 NOEL Gastrointestinal system, Lymphatic system
39 Week(s) Dog Oral (F) 6 mg/kg/day (3 mg/kg BID) NOEL None identified

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

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

MATERIAL SAFETY DATA SHEET

Material Name: Axitinib Film Coated Tablets
Revision date: 11-Jan-2012

Page 5 of 7
Version: 2.0

11. TOXICOLOGICAL INFORMATION

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):

Partition Coefficient 2.01 (axitinib)
(Measured - Log Pow/Log Kow):

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

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.

MATERIAL SAFETY DATA SHEET

Material Name: Axitinib Film Coated Tablets
Revision date: 11-Jan-2012

Page 6 of 7
Version: 2.0

15. REGULATORY INFORMATION

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

EU Risk Phrases:
R62 - Possible risk of impaired fertility.
R63 - Possible risk of harm to the unborn child.
R68 - Possible risk of irreversible effects.

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

OSHA Label:
WARNING
Suspected of damaging fertility or the unborn child.
Suspected of causing genetic defects.

Canada - WHMIS: Classifications

WHMIS hazard class:
D2b toxic materials



Croscarmellose sodium	
Australia (AICS):	Present
Lactose NF, monohydrate	
Australia (AICS):	Present
Magnesium Stearate	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3
Water, purified	
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	231-791-2

MATERIAL SAFETY DATA SHEET

Material Name: Axitinib Film Coated Tablets
Revision date: 11-Jan-2012

Page 7 of 7
Version: 2.0

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R62 - Possible risk of impaired fertility.

R63 - Possible risk of harm to the unborn child.

R68 - Possible risks of irreversible effects.

R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

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 12 - Ecological Information. Updated Section 11 - Toxicology Information.
Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients.

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