



MATERIAL SAFETY DATA SHEET

Revision date: 30-Aug-2005

Version: 1.0

Page 1 of 5

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017

Emergency telephone number: 1-212-573-2222
Hours of Operation - 24 Hours

Material Name: Sunitinib free base

Trade Name: Not applicable
Synonyms: PHA-290940
SU011248
Chemical Family: Not applicable
Intended Use: antineoplastic

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Sutent (free base)	557795-19-4	Not listed	100

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

3. HAZARDS IDENTIFICATION

Appearance: Dark yellow solid
Signal Word: WARNING

Statement of Hazard: May cause harm to the unborn child
May cause adverse effects on blood forming organs

Eye Contact: Minimal eye irritant in experimental animals .
Skin Contact: Not a skin irritant (based on animal data).
Inhalation: An Occupational Exposure Limit has been established for this substance; see Section 8.
Ingestion: Not acutely toxic (based on animal data).

Known Clinical Effects: Effects on blood and blood-forming organs have also occurred. Other commonly reported adverse effects include headache, nausea, and weakness/fatigue.

Potential Health Effects: Repeat-dose studies in animals have shown a potential to cause adverse effects on the hematological and reproductive systems.

EU Indication of danger: Toxic to reproduction, Category 2
Toxic

EU Hazard Symbols:



EU Risk Phrases:

R61 - May cause harm to the unborn child.
R48/25 - Toxic: danger of serious damage to health by prolonged exposure if swallowed.

MATERIAL SAFETY DATA SHEET

Material Name: Sunitinib free base
Revision date: 30-Aug-2005

Page 2 of 5
Version: 1.0

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.

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.

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.

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: Ground and bond all bulk transfer equipment. Enclosure is recommended to control airborne dust, mist or vapor levels. Avoid open handling. Prevent inhalation, contact with eye, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling.

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

MATERIAL SAFETY DATA SHEET

Material Name: Sunitinib free base
Revision date: 30-Aug-2005

Page 3 of 5
Version: 1.0

Sutent (free base)
Pfizer OEL TWA-8 Hr: 0.01 mg/m³

Analytical Method: Sunitinib malate: STP P 197.1 (contact Pfizer for additional details)

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal Protective Equipment:

Hands: Wear two layers of disposable gloves.
Eyes: Safety glasses or goggles. Avoid all hand to eye contact until gloves have been removed and hands washed.
Skin: Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
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:	Solid	Color:	Dark yellow
Molecular Formula:	C ₂₂ H ₂₇ FN ₄ O ₂	Molecular Weight:	398.48
Water solubility:	Not available		
Melting/Freezing Point (°C):	241 - 242		

10. STABILITY AND REACTIVITY

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

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

Sutent (free base)

Rat Oral Maximally Tolerated Dose >500 mg/kg
Mouse Oral Maximally Tolerated Dose >500mg/kg
Dog Oral Maximally Tolerated Dose >500mg/kg
Non-human Primate Oral Maximally Tolerated Dose >1200mg/kg
Inhalation Acute Toxicity 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)

Sutent (free base)

Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Mild

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

MATERIAL SAFETY DATA SHEET

Material Name: Sunitinib free base
Revision date: 30-Aug-2005

Page 4 of 5
Version: 1.0

Sutent (free base)

4 Week(s)	Rat	Oral	2.5 mg/kg/day	LOAEL	Bone marrow, Blood forming organs
28/56 Day(s)	Monkey	Oral	6.0 mg/kg/day	LOAEL	Bone Marrow, Blood forming organs
13 Week(s)	Non-human Primate	Oral	2.0 mg/kg/day	LOAEL	Bone Marrow, Blood forming organs
3 Month(s)	Rat	Oral	1.5 mg/kg/day	LOAEL	Bone Marrow, Blood forming organs
6 Month(s)	Rat	Oral	0.3 mg/kg/day	NOAEL	Bone Marrow

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

Sutent (free base)

Fertility & Early Embryonic Development-Females	Rat	Oral	1.5 mg/kg/day	NOAEL	Fetotoxicity
Fertility & Early Embryonic Development - Males	Rat	Oral	10 mg/kg/day	NOAEL	Fetotoxicity
Fertility & Early Embryonic Development-Females	Rat	Oral	5 mg/kg/day	NOAEL	Maternal Toxicity
Embryo / Fetal Development	Rat	Oral	3 mg/kg/day	NOAEL	Fetotoxicity
Embryo / Fetal Development	Rat	Oral	5 mg/kg/day	NOAEL	Maternal Toxicity

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

Sutent (free base)

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
Mammalian Cell Mutagenicity		Negative
Chromosome Aberration	Human Lymphocytes	Negative
<i>In Vitro</i> Micronucleus		Negative

Carcinogen Status: Not listed as a carcinogen by IARC, NTP or US OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Incineration is the recommended method of disposal for this material. Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

MATERIAL SAFETY DATA SHEET

Material Name: Sunitinib free base
Revision date: 30-Aug-2005

Page 5 of 5
Version: 1.0

EU Labeling: T
EU Indication of danger: Toxic to reproduction, Category 2
Toxic
EU Risk Phrases:
R61 - May cause harm to the unborn child.
R48/25 - Toxic: danger of serious damage to health by prolonged exposure if swallowed.
EU Safety Phrases:
S22 - Do not breathe dust.
S53 - Avoid exposure - obtain special instructions before use.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING
May cause harm to the unborn child
May cause adverse effects on blood forming organs

Canada - WHMIS: Classifications

WHMIS hazard class:
D2a very toxic materials



16. OTHER INFORMATION

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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.

End of Safety Data Sheet