



MATERIAL SAFETY DATA SHEET

Revision date: 05-Jan-2007

Version: 1.1

Page 1 of 6

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

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

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Sunitinib Malate Capsules

Trade Name: Sutent®
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as Antineoplastic.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Sunitinib malate	341031-54-7	Not listed	<40
Magnesium stearate	557-04-0	209-150-3	*

Ingredient	CAS Number	EU EINECS List	%
Croscarmellose sodium	74811-65-7	Not listed	*
Hard gelatin capsules	MIXTURE	Not listed	*
Mannitol	69-65-8	200-711-8	*
Povidone	9003-39-8	Not listed	*
Water, purified	7732-18-5	231-791-2	###

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

3. HAZARDS IDENTIFICATION

Appearance: Orange; brown opaque capsules .
Signal Word: WARNING

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

Additional Hazard Information:

Short Term: May cause eye irritation; Not a skin irritant ; Not acutely toxic (based on components)
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on the hematological and reproductive systems.

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

MATERIAL SAFETY DATA SHEET

Material Name: Sunitinib Malate Capsules
Revision date: 05-Jan-2007

Page 2 of 6
Version: 1.1

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

EU Hazard Symbols:



EU Risk Phrases:

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

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: Not applicable

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.

MATERIAL SAFETY DATA SHEET

Material Name: Sunitinib Malate Capsules
Revision date: 05-Jan-2007

Page 3 of 6
Version: 1.1

7. HANDLING AND STORAGE

General Handling: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Avoid generating airborne dust.

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Sunitinib malate
Pfizer OEL TWA-8 Hr: 0.01 mg/m³

Magnesium stearate
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA
The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Analytical Method: Analytical method available for sunitinib malate. Contact Pfizer Inc for further information.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

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: Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly after handling this product.
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:	Capsule	Color:	Orange; opaque brown.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
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)

MATERIAL SAFETY DATA SHEET

Material Name: Sunitinib Malate Capsules
Revision date: 05-Jan-2007

Page 4 of 6
Version: 1.1

Sunitinib malate

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

Mannitol

Rat Oral LD 50 13500 mg/kg
Mouse Oral LD 50 22 g/kg

Povidone

Rat Oral LD50 100 g/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

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)

Sunitinib malate

Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Mild

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

Sunitinib malate

4 Week(s) Rat Oral 5 mg/kg/day NOEL Bone marrow, Blood forming organs
28/56 Day(s) Monkey Oral 6.0 mg/kg/day LOEL Bone Marrow, Blood forming organs
13 Week(s) Non-human Primate Oral 2.0 mg/kg/day LOEL Bone Marrow, Blood forming organs
3 Month(s) Rat Oral 1.5 mg/kg/day NOEL Bone Marrow, Blood forming organs
6 Month(s) Rat Oral 0.3 mg/kg/day NOEL Bone Marrow

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

Sunitinib malate

Fertility & Early Embryonic Development-Females Rat Oral 1.5 mg/kg/day NOEL Fetotoxicity
Embryo / Fetal Development Rabbit Oral 0.5 mg/kg/day NOEL Fetotoxicity
Embryo / Fetal Development Rabbit Oral 1.0 mg/kg/day NOEL Maternal Toxicity
Embryo / Fetal Development Rat Oral 3 mg/kg/day NOEL Fetotoxicity
Embryo / Fetal Development Rat Oral 5 mg/kg/day NOEL Maternal Toxicity

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

Sunitinib malate

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

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

Povidone

IARC: Group 3

MATERIAL SAFETY DATA SHEET

Material Name: Sunitinib Malate Capsules
Revision date: 05-Jan-2007

Page 5 of 6
Version: 1.1

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: 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

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

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

EU Safety Phrases:
S36/37 - Wear suitable protective clothing and gloves.
S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
S53 - Avoid exposure - obtain special instructions before use.

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

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A

MATERIAL SAFETY DATA SHEET

Material Name: Sunitinib Malate Capsules
Revision date: 05-Jan-2007

Page 6 of 6
Version: 1.1



Croscarmellose sodium	
Australia (AICS):	Present
Magnesium stearate	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	209-150-3
Mannitol	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-711-8
Povidone	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Water, purified	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 13 - Disposal Considerations.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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