MATERIAL SAFETY DATA SHEET

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:
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. HAZARDS IDENTIFICATION

Appearance: Orange; brown opaque hard gelatin capsules .
Signal Word: DANGER

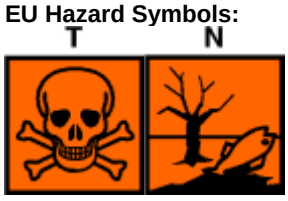
Statement of Hazard:
May damage the unborn child.
May cause damage to blood forming organs through prolonged or repeated exposure.
Very toxic to aquatic life with long lasting effects.

Additional Hazard Information:
Short Term: May cause mild eye irritation. (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: Common adverse effects include fatigue, gastrointestinal disturbances, hematological effects, and skin effects. Other, more serious, effects include changes in liver function, liver failure

EU Indication of danger:
Toxic to reproduction, Category 2
Dangerous for the Environment

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.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

2. HAZARDS IDENTIFICATION

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Sunitinib malate	341031-54-7	Not Listed	T;R48/25 N;R50/53 Repr.Cat2;R61	15-40
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

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

Additional Information: * Proprietary
as required
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: 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.

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 hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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.

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.

Sunitinib malate

Pfizer OEL TWA-8 Hr:	10 µg/m^3,

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m^3 TWA
Australia TWA	10 mg/m^3
Belgium OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

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. 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.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Capsule	**Color:**	Orange; opaque brown.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Chemical 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)

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/m^3

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

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.

11. TOXICOLOGICAL INFORMATION

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 NOAEL 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 NOAEL 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))

Sunitinib malate
Fertility & Early Embryonic Development-Females Rat Oral 1.5 mg/kg/day NOAEL Fetotoxicity
Embryo / Fetal Development Rabbit Oral 0.5 mg/kg/day NOAEL Fetotoxicity
Embryo / Fetal Development Rabbit Oral 1.0 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)

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

Sunitinib malate
6 Month(s) Mouse Female Oral 8 mg/kg/day NOEL Gastrointestinal system
6 Month(s) Mouse Male Oral 25 mg/kg/day NOEL Gastrointestinal system

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

Povidone
IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Very toxic to aquatic life with long lasting effects. Releases to the environment should be avoided. See aquatic toxicity data, below:

Mobility, Persistence and Degradability: Not readily biodegradable (8.8 % after 28 days). (sunitinib malate)

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

Sunitinib malate
Daphnia magna (Water Flea) OECD EC50 48 Hours 3.1 mg/L
Oncorhynchus mykiss (Rainbow Trout) OECD LC50 96 Hours 7.8 mg/L

12. ECOLOGICAL INFORMATION

Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 Hours 0.32 mg/L
Daphnia magna (Water Flea) OECD NOEC 21 Days 0.053 mg/L
Ceriodaphnia dubia (Daphnids) EPA NOEC 7 Days 0.32 mg/L
Pimephales promelas (Fathead Minnow) OECD NOEC 32 Days 0.00027 mg/L

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

Sunitinib malate
Activated sludge OECD EC50 3 Hours 574 mg/L
Clostridium perfingens FDA MIC 24 Hours 80 mg/L
Bacillus subtilis (Bacterium) FDA MIC 26 Hours 80 mg/L
Nostoc sp. (Freshwater Cyanobacteria) FDA MIC 7 Days 5.0 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.

15. REGULATORY INFORMATION

EU Symbol: T ; N
EU Indication of danger: Toxic to reproduction, Category 2
Dangerous for the Environment

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.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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.

15. REGULATORY INFORMATION

OSHA Label:
DANGER
May damage the unborn child.
May cause damage to blood forming organs through prolonged or repeated exposure.
Very toxic to aquatic life with long lasting effects.

Canada - WHMIS: Classifications

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

Mannitol

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-711-8

Croscarmellose sodium

Australia (AICS):	Listed

Povidone

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	209-150-3

Water, purified

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R61 - May cause harm to the unborn child.
R48/25 - Toxic: danger of serious damage to health by prolonged exposure if swallowed.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 2 - Hazard Identification.

Prepared by: Product Stewardship Hazard Communications
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