SAFETY DATA SHEET		
Product Name	Sunitinib Malate Capsules 12.5 mg, 25 mg and 50 mg / Sunitinib 12.5 mg, 25 mg and 50 mg Hard Capsules	Page No **1 of 9**

1. PRODUCT INFORMATION

Product Name: Sunitinib Malate Capsules 12.5 mg, 25 mg and 50 mg / Sunitinib 12.5 mg, 25 mg and 50 mg Hard Capsules

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture
GHS - Classification

Reproductive Toxicity: Category 1B

Specific target organ systemic toxicity (repeated exposure): Category 1

Acute aquatic toxicity: Category 1

Chronic aquatic toxicity: Category 1

Label Elements

Signal Word: Danger

Hazard Statements:

H360D - May damage the unborn child
H372 - Causes damage to organs through prolonged or repeated exposure
H400 - Very toxic to aquatic life
H410 - Very toxic to aquatic life with long lasting effects

Precautionary Statements:

P201 - Obtain special instructions before use
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
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P314 - Get medical attention/advice if you feel unwell
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

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

Additional Information:

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.

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

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: Not applicable

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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 / Contain the source of spill if it is safe to do so. Collect spilled material by a method that **Collecting:** 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.

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 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage :
US: Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see United States Pharmacopoeia (USP) Controlled Room Temperature].
Europe: Does not require any special storage conditions.
Specific end use(s): Pharmaceutical drug product; Antineoplastic

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Sunitinib malate / Sunitinib
Pfizer OEL TWA-8 Hr: 10 $\mu g/m^3$

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

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 disposable gloves (e.g. Nitrile, etc.) (double 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 thes tandards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious disposable 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 full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Capsule	**Color:**	Caramel opaque.
Odor:	No data available.	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**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.		

12.5 mg : Size "4" hard gelatin capsules with Orange opaque body imprinted with "6" and Orange opaque cap imprinted with "MS" in white ink, free from physical defects.

25 mg : Size "3" hard gelatin capsules with Orange opaque body imprinted with "7" and Caramel opaque cap imprinted with "MS" in white ink, free from physical defects

37.5 mg : Size "3" hard gelatin capsules with Yellow opaque body imprinted with "8" and Yellow opaque cap imprinted with "MS" in black ink, free from physical defects
50 mg : Size '2' hard gelatin capsules with Caramel opaque body imprinted with "9" and Caramel opaque cap imprinted with "MS" in white ink, free from physical defects

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:	None known
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.
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

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 / Sunitinib

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
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 / Sunitinib

Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Mild

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

Sunitinib malate / Sunitinib

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 / Sunitinib
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 / Sunitinib

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 / Sunitinib

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
2 Year(s)	Rat	Oral	1 mg/kg/day	LOAEL	Tumors

Carcinogen Status:

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

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:

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

Sunitinib malate / Sunitinib

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

Activated sludge	OECD	EC50	574 mg/L
Clostridium perfingens	FDA	MIC	80 mg/L
Bacillus subtilis (Bacterium)	FDA	MIC	80 mg/L
Nostoc sp. (Freshwater Cyanobacteria)	FDA	MIC	5.0 mg/L

Persistence and Degradability: No data available

Sunitinib malate / Sunitinib
OECD Soil (various) Ready 8.8% After 28 Day(s)

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATION

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.

This material is regulated for transportation as a hazardous material/dangerous good.

UN number:	UN 3077
UN proper shipping name:	Environmentally Hazardous Substance, Solid, n.o.s (Sunitinib malate / Sunitinib)
Transport hazard class(es):	9
Packing group:	III
Environmental Hazard(s):	Marine Pollutant

5 kg/5L Exception:
UN3082 and UN3077 materials contained in good quality packaging in the quantities listed below are not regulated as dangerous goods for transport by any mode:

* Single packagings containing a net quantity of 5 liters or less for liquids or a net mass of 5 kg or less for solids.
* Combination packagings containing a net quantity per inner packaging of 5 liters or less for liquids or a net mass of 5 kg or less for solids.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Sunitinib malate / Sunitinib	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
Mannitol	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
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	200-711-8
Croscarmellose sodium	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
Hard gelatin capsules	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
Magnesium stearate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present

Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3
Povidone	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.1B; H360D - May damage the unborn child
Specific target organ toxicity, repeated exposure-Cat.1; 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. Safety data sheets for individual ingredients.

Product Stewardship Hazard Communication