



MATERIAL SAFETY DATA SHEET

Bayer Pharmaceuticals Corporation
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TRANSPORTATION EMERGENCY
CALL CHEMTREC..... : (800) 424-9300
INTERNATIONAL : (703) 527-3887

NON-TRANSPORTATION
BAYER EMERGENCY PHONE : (203) 812-2000
BAYER INFORMATION PHONE: (800) 662-2927

Section 1: Product and Company Identification

Product Name: Nexavar
Material Number: 8917879
Synonyms: Sorafenib tosylate tablets (200 mg)

Section 2: Composition/Information on Ingredients

HAZARDOUS INGREDIENTS

<u>Ingredient Name/ CAS Number</u>	<u>Exposure Limits</u>	<u>Concentration</u>	
		<u>Min.</u>	<u>Max.</u>
This material is not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.			

Section 3: Hazards Identification

EMERGENCY OVERVIEW

Color: Red **Form:** Solid Tablets **Odor:** Odorless
Product poses little or no hazard if spilled and no unusual hazard if involved in a fire. See Potential Health Effects if the recommended dosage is exceeded.

POTENTIAL HEALTH EFFECTS

Route(s) of Entry: Accidental;, Inhalation, Skin Contact, Eye Contact, Appropriate route of entry:, Ingestion

HUMAN EFFECTS AND SYMPTOMS OF OVEREXPOSURE

General Effects of Exposure
Acute Effects of Exposure: Overexposure may cause nausea, vomiting, decreased appetite,

diarrhea, stool discoloration.

Chronic Effects of Exposure: Chronic overexposure to this product may cause effects as noted under acute overexposure.

Carcinogenic Components:

NTP: None

IARC: None

OSHA: None

Medical Conditions Aggravated by Exposure: None known.

Human Health Effects Postnote: Use only as directed. See product packaging and the Physicians' Desk Reference (PDR) for further information concerning adverse effects and drug interaction precautions. This is a pharmaceutical material.

Section 4: First Aid Measures

First Aid for Eye: In case of contact, flush eyes with plenty of lukewarm water. Use fingers to ensure that eyelids are separated and that the eye is being irrigated. Contact a physician or call 203-812-2000.

First Aid for Skin: In case of skin contact, wash affected areas with soap and water. Get medical attention if irritation develops or persists.

First Aid for Inhalation: Not applicable.

First Aid for Ingestion: Contact poison control center or 203-812-2000.

Section 5: Fire Fighting Measures

Flash Point: Not Applicable

Flammable Limits:

Upper Explosion Limit (UEL %): Not Applicable

Lower Explosion Limit (LEL %): Not Applicable

Auto-ignition Temperature: Not Applicable

Extinguishing Media:

Suitable: Water, Dry Chemical, Foam

Special Fire Fighting Procedures: Avoid dusting. Dust can form explosive mixtures with air. Firefighters should be equipped with self-contained breathing apparatus to protect against potentially toxic and irritating fumes.

Section 6: Accidental Release Measures

Spill or Leak Procedures: Spills should be swept up and placed in appropriate containers for disposal. Prevent from entering open drains and waterways. Avoid creating dusty conditions.

Section 7: Handling and Storage

Storage Temperature: Store in a cool dry place.
Minimum: 59 °F (15 °C)
Maximum: 86 °F (30 °C)

Shelf Life: Do not use after expiration date.

Special Sensitivity: Do not expose to light when in solution.

Handling/Storage Precautions: Keep this and all drugs out of the reach of children. Wash thoroughly after handling. Containers should be kept tightly closed to prevent contamination. Use normal precautions for storage of a drug. Avoid contact with eyes. Avoid excessive contact with skin or clothing.

Section 8: Exposure Controls/Personal Protection

Personal Protection Equipment

Eye Protection Requirements: Chemical safety goggles or glasses.

Skin Protection Requirements: Lab coat., Gloves, long sleeved shirts and pants., Employees should wash their hands and face before eating, drinking or using tobacco products.

Ventilation Requirements: Under normal conditions of use, special ventilation is not required.

Respirator Requirements: A NIOSH approved dust respirator should be worn if inhalation of dust is a problem.

Work Practices: Use caution. Use good personal hygiene - wash hands and exposed skin thoroughly with soap and water after each use.

Additional Protective Measures: Employers shall provide handwashing facilities which are readily accessible to employees. Educate and train employees in the safe use and handling of this product.

Section 9: Physical and Chemical Properties

Physical Form: Solid
Appearance: Tablets
Color: Red

Odor:	Odorless
pH:	Not Applicable
Boiling Point:	Not Applicable
Melting/Freezing Point:	Not Applicable
Solubility in Water:	Very low solubility
Specific Gravity:	Not Established
Bulk Density:	Not Established
Vapor Pressure:	Not Established

Section 10: Stability and Reactivity

Stability:	Stable
Hazardous Polymerization:	Will not occur
Substances to Avoid:	Oxidizing agents, See product packaging and the Physicians' Desk Reference (PDR) for drug interaction.
Conditions to Avoid:	High humidity
Decomposition Products:	None known.

Section 11: Toxicological Information

Toxicity Data for Nexavar

Section 12: Ecological Information

Ecological Data for Nexavar

Section 13: Disposal Considerations

Waste Disposal Method:	Waste disposal should be in accordance with existing federal, state and local environmental control laws.
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Section 14: Transportation Information

Technical shipping name:	Pharmaceutical
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Domestic Surface Transportation (DOT)

Hazard Class or Division:	Non-Regulated
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Marine Transportation (IMO / IMDG)

Hazard Class Division Non-Regulated
Number:

Air Transportation (ICAO / IATA)

Hazard Class Division Non-Regulated
Number:

Section 15: Regulatory Information

United States Federal Regulations

OSHA Hazcom Standard Not subject to OSHA
Rating:

TSCA Inventory List: This product is exempt from TSCA under Section 3 (2)(B)(vi) when used for pharmaceutical application.

CERCLA Hazardous Substance:

<u>Component(s)</u>	<u>Reportable Quantity</u>
None	

SARA Title III

SARA Section 302 Extremely Hazardous Substances:

<u>Component(s)/ CAS Number</u>	<u>Concentration</u>	
	<u>Min.</u>	<u>Max.</u>
Exempt		

SARA Section 313 Toxic Chemicals:

<u>Component(s)/ CAS Number</u>	<u>Reporting Threshold</u>	<u>Concentration</u>	
		<u>Min.</u>	<u>Max.</u>
Exempt			

RCRA Status: If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24)

The following chemicals are specifically listed by individual states; other product specific health and safety data in other sections of the MSDS may also be applicable for state requirements. For details on your regulatory requirements you should contact the appropriate agency in your state.

State Right-to-Know Information

<u>Component(s)/ CAS Number</u>	<u>State Code</u>	<u>Concentration</u>	
		<u>Min.</u>	<u>Max.</u>

State Code Translation Table

Section 16: Other Information

Material Name: Nexavar

Article Number: 8917879

HMIS Rating

Health		1
Flammability		1
Reactivity		0

0=Minimal 1=Slight 2=Moderate 3=Serious 4=Severe
*=Chronic Health Hazard

Bayer Pharmaceuticals Corporation's method of hazard communication is comprised of Product Labels and Material Safety Data Sheets. HMIS and NFPA ratings are provided by Bayer Pharmaceuticals Corporation as a customer service.

Contact: Bill Galdenzi
Phone: (203) 812-3132
MSDS Number: 000000002142
Version Date: 10/13/2005
MSDS Version: 1.3

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|| Indicates Relevant Change Made.