



SAFETY DATA SHEET

122000002374

Nexavar® Tablets or Powder

Version 2.0

Revision Date 06/30/2010

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**Product information**

Product Name: Nexavar® Tablets or Powder
Generic name: Sorafenib
MSDS Number: 122000002374

Use : Medicinal products

Company

BAYER HEALTHCARE LLC
Bayer HealthCare Pharmaceuticals Inc.
6 West Belt
Wayne, NJ 07470
UNITED STATES
1888-84-BAYER

In case of emergency: 1888-84-BAYER
Chemtrec: (800) 424-9300

2. HAZARDS IDENTIFICATION**Emergency Overview**

Colour: grey, brown **Form:** solid, tablet, powder **Odour:** odourless.
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. Appropriate route of entry: Ingestion Accidental: Inhalation Skin contact Eye contact

Hazard Communication (29CFR 1910.1200)

Acute Effects of Exposure	Acute overexposure to this product may cause nausea and vomiting. Diarrhoea
Chronic Effects of Exposure	Chronic overexposure to this product may cause effects as noted under acute overexposure.
Medical Conditions Aggravated by Exposure	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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

This material is not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

Label Ingredients: Croscarmellose sodium; Hydroxypropylmethylcellulose; Magnesium Stearate; Dodecylhydrogensulfat Natrium Salz; Polyethylene Glycol; Iron Hydroxide Oxide Yellow; Iron oxide; Microcrystalline Cellulose; Titanium Dioxide (color);

Other Ingredients

Weight percent	Components	CAS-No.
50 - 80%	Sorafenib Tosylat (Bay 54-9085)	475207-59-1

4. FIRST AID MEASURES

General advice: Take off all contaminated clothing immediately.

If inhaled: Remove to fresh air. If symptoms persist, call a physician.

In case of skin contact: After contact with skin, wash immediately with plenty of soap and water. If skin reactions occur, contact a physician.

In case of eye contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

If swallowed: If swallowed, seek medical advice immediately and show this container or label.

Contact Number: Use the Bayer Emergency Number in Section 1

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Any

Specific hazards during fire fighting: Fire may cause evolution of: Carbon monoxide Carbon dioxide (CO₂)

Special protective equipment for fire-fighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Further information: Prevent fire extinguishing water from contaminating surface water or the ground water system.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment.

Methods for cleaning up: Place in closed containers. Label for proper disposal.

Additional advice: Avoid dust formation.

Further Accidental Release Notes Avoid dust formation.

7. HANDLING AND STORAGE

Handling:

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 skin, eyes and clothing.

Take measures to prevent the build up of electrostatic charge. Keep away from open flames, hot surfaces and sources of ignition.

Storage:

Do not expose to light.

Storage temperature: 59 - 86 °F (15 - 30 °C)

Do not use after expiration date.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory protection:

Recommended Filter type: HEPA

Hand protection:

Chemically resistant gloves.

Eye protection:

Protective goggles

Other protective measures:

Wear suitable protective equipment.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form:	solid, tablet, powder
Colour:	grey, brown
Odour:	odourless
Melting point:	219 °C
Density:	no data available

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Bulk density:	no data available
Vapour pressure:	not applicable
Water solubility:	slightly soluble
pH:	no data available
Partition coefficient (n-octanol/water):	no data available
Solubility in organic solvents:	no data available
Ignition temperature:	no data available

10. STABILITY AND REACTIVITY

Conditions to avoid: no data available

Materials to avoid: Oxidizing agents

Hazardous reactions: None known.

Thermal decomposition:

no data available

Hazardous decomposition products:

Carbon monoxide, Carbon dioxide (CO₂)

11. TOXICOLOGICAL INFORMATION

Acute oral toxicity:

Sorafenib Tosylat (Bay 54-9085)

LD50 rat: > 2,000 mg/kg

Method: OECD Test Guideline 401

LD50 mouse: > 2,000 mg/kg

Genotoxicity in vitro:

Sorafenib Tosylat (Bay 54-9085)

Ames test Mutagenicity (Salmonella typhimurium - reverse mutation assay)

Result: negative

In vitro Cytogenetic Test (Hamster V79-cells)

Result: clastogenic effects

Method: Mutagenicity (in vitro mammalian cytogenetic test)

Chromosome aberration test in vitro

Dose: no

Result: negative

Chromosome aberration test in vitro

Dose: Yes

Result: positive

Genotoxicity in vivo:

Sorafenib Tosylat (Bay 54-9085)

mouse, intraperitoneal

Result: No indication of clastogenic effects.

Method: OECD TG 474

Pharmaceutic effects:

anti-cancer drug

CMR classification:

Mutagenicity: Negative Salmonella/microsome (Ames test). Negative in vitro chromosome aberration test without metabolic activation; positive with metabolic activation. Negative in vivo micronucleus test in male mice.

12. ECOLOGICAL INFORMATION

General advice:

Do not allow to enter surface waters or groundwater.

Toxicity to daphnia and other aquatic invertebrates:

Sorafenib Tosylat (Bay 54-9085)

EC10 141 mg/l

Test species: Daphnia magna (Water flea)

Toxicity to algae:

Sorafenib Tosylat (Bay 54-9085)

Growth inhibition tested on: Desmodesmus subspicatus (Green algae)

No concentration-dependent effects in the growth inhibition test.

Toxicity to bacteria:

Sorafenib Tosylat (Bay 54-9085)

tested on: activated sludge micro-organism

No concentration-dependent effects in the respiration inhibitory test

Biodegradability:

Sorafenib Tosylat (Bay 54-9085)

0 %, 28 d Not readily biodegradable.

Method: OECD TG 301 F

13. DISPOSAL CONSIDERATIONS

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)

Waste disposal should be in accordance with existing federal, state and local environmental control laws.

14. TRANSPORT INFORMATION

Land transport (DOT)
Non-Regulated

Inland waterway transport
Non-Regulated

Railway transport
Non-Regulated

Sea transport (IMDG)
Non-Regulated

Air transport (ICAO / IATA cargo aircraft only)
Non-Regulated

Air transport (ICAO / IATA passenger and cargo aircraft)
Non-Regulated

15. REGULATORY INFORMATION

US. Toxic Substances Control Act This product is exempt from TSCA under Section 3 (2)(B)(vi) when used for pharmaceutical application.

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A) Components
None

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) - Supplier Notification Required Components
None

US. EPA CERCLA Hazardous Substances (40 CFR 302) Components
None

Massachusetts, New Jersey or Pennsylvania Right to Know Substance Lists

Weight percent	Components	CAS-No.
3 - 7%	Cellulose microcrystalline	9004-34-6

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California Prop. 65

To the best of our knowledge, this product does not contain any of the listed chemicals, which the state of California has found to cause cancer, birth defects or other reproductive harm.

OSHA Hazcom Standard Rating Non-Hazardous

16. OTHER INFORMATION

HMIS Rating

Health	1
Flammability	0
Physical Hazard	0

0=Minimal 1=Slight 2=Moderate 3=Serious 4=Severe

* = Chronic Health Hazard

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.