

Safety Data Sheet (SDS) According to the OSHA Hazard Communication Standard 29 CFR 1910.1200

Issuing Date: 2018-03-23

Version: 1

SECTION 1. Identification

Product identifier

Product No 8705
Product name Sorafenib
Other means of identification 8705S

Recommended use of the chemical and restrictions on use

Identified uses This product is intended for research purposes only.
Manufacturer, importer, supplier

Manufacturer address Cell Signaling Technology, Inc.
 3 Trask Lane
 Danvers, MA 01923
 United States
 TEL: +1 978 867 2300
 FAX: +1 978 867 2400

Website www.cellsignal.com
Email address support@cellsignal.com
Emergency telephone number In case of emergency call CHEMTREC 1-800-424-9300

SECTION 2. Hazard(s) identification

Classification

This substance/mixture is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Reproductive toxicity	Category 1B
Specific target organ toxicity - repeated exposure (STOT RE)	Category 2

GHS Label elements, including precautionary statements



Signal Word
 Danger

Hazard statement(s)
 May damage fertility or the unborn child. May cause damage to organs through prolonged or repeated exposure.

Precautionary Statement(s)
 Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe

dust/fume/gas/mist/vapors/spray. Wear protective gloves/protective clothing/eye protection/face protection.
 IF exposed or concerned: Get medical advice/attention.
 Store locked up.
 Dispose of contents/container to an approved waste disposal plant.

Supplementary Hazard Information

No information available.

Hazards not otherwise classified (HNOC)

Not applicable.

SECTION 3. Composition/information on ingredients

Formula	C ₂₁ H ₁₆ ClF ₃ N ₄ O ₃ •C ₇ H ₈ O ₃ S
Molecular Weight	637.03 g/mol
Chemical nature	Monoconstituent substance
Synonyms	Sorafenib tosylate; Nexavar™; 4-[4-[[4-chloro-3-(trifluoromethyl)phenyl]carbamoylamino]phenoxy]-N-methylpyridine-2-carboxamide;4-methylbenzenesulfonic acid

Chemical Name	CAS No	Weight %
2-Pyridinecarboxamide, 4-(4-(((4-chloro-3-(trifluoromethyl)phenyl)amino)carbonyl)amino)phenoxy)-N-methyl-, mono(4-methylbenzenesulfonate)	475207-59-1	100

SECTION 4. First-aid measures

Eye contact	Rinse thoroughly with plenty of water, also under the eyelids. Keep eye wide open while rinsing.
Skin contact	Immediate medical attention is required. Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.
Inhalation	Immediate medical attention is required. Move to fresh air. If not breathing, give artificial respiration.
Ingestion	Do NOT induce vomiting. Immediate medical attention is required. Never give anything by mouth to an unconscious person. Drink plenty of water.

Most important symptoms and effects, both acute and delayed

Diarrhea. Fatigue. infection. rash. Loss of appetite. Nausea. hand-foot skin reaction. Gastrointestinal discomfort. hypertension. Hemorrhage. alopecia.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

Advice for emergency responders

General advice	Immediate medical attention is required. Show this safety data sheet to the doctor in attendance.
Protection of first-aiders	Use personal protective equipment. Avoid contact with skin, eyes and clothing.

SECTION 5. Fire-fighting measures

Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the
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surrounding environment.

Unsuitable Extinguishing Media CAUTION: Use of water spray when fighting fire may be inefficient.

Specific hazards arising from the chemical

No information available.

Explosion Data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Ensure adequate ventilation.

Other information No information available.

Environmental precautions

Do not flush into surface water or sanitary sewer system.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Use personal protective equipment. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid dust formation. Clean contaminated surface thoroughly.

SECTION 7. Handling and storage

Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical measures/Storage conditions Keep containers tightly closed in a dry, cool and well-ventilated place.

Packaging material No information available.

Incompatible products None known based on information supplied.

SECTION 8. Exposure controls/personal protection

Control parameters

Appropriate engineering controls

Showers, eyewash stations, and ventilation systems.

Individual protection measures, such as personal protective equipment

Personal protective equipment (PPE) needs to be selected depending on the implemented engineering controls, frequency/duration of work activities and the concentrations of the hazardous substance.

Eye/face protection	Tightly fitting safety goggles
Skin and body protection	Wear protective gloves/clothing.
Respiratory protection	If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.
Hygiene measures	When using, do not eat, drink or smoke. Provide regular cleaning of equipment, work area and clothing. Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. Keep away from food, drink and animal feeding stuffs.

SECTION 9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Solid	Color	Off-white
Appearance	Crystalline Powder	Odor Threshold	No information available
Odor	No information available		

<u>Property</u>	<u>Values</u>	<u>Remarks</u>	<u>Method</u>
pH	No information available		
Melting point/freezing point	231-238 °C		
Initial boiling point and boiling range			
Flash point		-	
Evaporation rate	No information available		
Flammability (solid, gas)	No information available		
Upper flammability limit	No information available		
Lower flammability limit	No information available		
Vapor pressure	No information available		
Vapor density	No information available		
Relative density	No information available		
Solubility	Sparingly soluble in aqueous buffers		
Solubility in other solvents	No information available.		
Partition coefficient: n-octanol/water	No information available		
Autoignition temperature	No information available		
Decomposition temperature	No information available		
Viscosity	No information available		
Viscosity, dynamic	No information available		
Explosive properties	No information available		
Oxidizing properties	No information available		

Other information

Softening point	No information available
Molecular Weight	637.03
VOC content	No information available
Density	No information available.
Bulk Density VALUE	No information available.

SECTION 10. Stability and reactivity

Reactivity

No information available.

Chemical stability

Stable under recommended storage conditions.

Possibility of hazardous reactions

Hazardous reactions	None under normal processing.
Hazardous polymerization	None under normal processing.

Conditions to Avoid

No information available.

Incompatible Materials

None known based on information supplied.

Hazardous Decomposition Products

None known based on information supplied.

SECTION 11. Toxicological information

Information on likely routes of exposure

Inhalation	There is no data available for this product.
Eye contact	There is no data available for this product.
Skin contact	There is no data available for this product.
Ingestion	Reproductive Toxicity. Target Organ Effects.

Information on toxicological effects

This material should only be handled by, or under the close supervision of, those properly qualified in the handling and use of potentially hazardous chemicals. It should be borne in mind that the toxicological and physiological properties of this compound is not well defined.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Symptoms	Diarrhea. Fatigue. infection. rash. Loss of appetite. Nausea. hand-foot skin reaction. Gastrointestinal discomfort. hypertension. Hemorrhage. alopecia.
Sensitization	No information available.
Mutagenic effects	The weight of evidence demonstrates that this material is not genotoxic. Sorafenib was clastogenic when tested in an in vitro mammalian cell assay (Chinese hamster ovary) in the presence of metabolic activation. Sorafenib was not mutagenic in the in vitro Ames bacterial cell assay or clastogenic in an in vivo mouse micronucleus assay.
Carcinogenicity	No component of this product present at levels greater than or equal to 0.1% is identifiable as probable, possible or confirmed carcinogen by IARC, ACGIH, NTP, or OSHA.
Reproductive toxicity	This material is classified as a Pregnancy Category D: Positive evidence of risk. When administered to rats and rabbits during the period of organogenesis, sorafenib was teratogenic and induced embryo-fetal toxicity (including increased post-implantation loss, resorptions, skeletal retardations, and retarded fetal weight). Adverse intrauterine development effects were seen at doses =0.2 mg/kg/day (1.2 mg/m2/day) in rats and 0.3 mg/kg/day (3.6 mg/m2/day) in rabbits. Results from the repeat-dose toxicity studies suggest there is a potential for sorafenib to impair reproductive function and fertility. Typical changes in rats consisted of testicular atrophy or degeneration, degeneration of epididymis, prostate, and seminal vesicles, central necrosis of the corpora lutea and arrested follicular development. Sorafenib-related effects on the reproductive organs of rats were manifested at daily oral doses = 5 mg/kg (30 mg/m2).
STOT - single exposure	No information available.
STOT - repeated exposure	Reproductive system. Heart. Cardiovascular system.
Neurological effects	No information available.
Aspiration Hazard	No information available.

SECTION 12. Ecological information

Ecotoxicity

100% of the mixture consists of components of unknown hazards to the aquatic environment.

Persistence and degradability No information available.
Bioaccumulation No information available.
Mobility No information available

Other adverse effects

No information available.

SECTION 13. Disposal considerations

Waste Disposal Methods

Should not be released into the environment.

Disposal considerations

Do not empty into drains; dispose of this material and its container in a safe way.

SECTION 14. Transport information


This material is not subject to regulation as a hazardous material for shipping.

SECTION 15. Regulatory information

North American Inventory Listing

Chemical Name	TSCA 8(b)	TSCA 12(b)	DSL	NDSL
2-Pyridinecarboxamide, 4-(4-(((4-chloro-3-(trifluoromethyl)phenyl)amino)carbonyl)amino)phenoxy)-N-methyl-, mono(4-methylbenzenesulfonate)	Not Listed	Not Listed	Not Listed	Not Listed

Canadian Workplace Hazardous Materials Information System (WHMIS) Classification

	Class D2A - Very Toxic Material at $\geq 0.1\%$
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SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute Health Hazard No
Chronic Health Hazard Yes

Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

Clean Water Act

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. FIFRA Label Information

This product does not contain any substances regulated as pesticides.

US Commerce Department - Export Administration Regulations Information

This product does not contain any substances regulated under the Chemical Weapons Convention (CWC).

U.S. Drug Enforcement Administration Information

This product does not contain any substances regulated under the DEA.

SECTION 16. Other information

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Disclaimer

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.

End of Safety Data Sheet