



SAFETY DATA SHEET (SDS): According to the OSHA Hazard Communication Standard 29 CFR 1910.1200
Issuing Date: 2015-01-15 Revision Date: 2015-01-16

Version: 2

SECTION 1. Identification

Product identifier

Product number 12328
Product name Sunitinib
Other means of identification 12328S

Recommended use of the chemical and restrictions on use

Identified uses This product is intended for research purposes only.
Uses advised against This product is not intended for use in diagnostic procedures or therapeutics.
This product is not intended for use in humans or animals.

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
Company phone number 978-867-2300
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)

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

GHS Label elements, including precautionary statements



Signal Word
Danger

Hazard statement(s)

Suspected of causing cancer
 May damage fertility or the unborn child
 Causes 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
 Use personal protective equipment as required
 Do not breathe dust/fume/gas/mist/vapors/spray
 Wash face, hands and any exposed skin thoroughly after handling
 Do not eat, drink or smoke when using this product
 IF exposed or concerned: Get medical advice/attention
 Store locked up
 Dispose of contents/container to an approved waste disposal plant

Supplementary Hazard Information

Hazards not otherwise classified (HNOC) None

SECTION 3. Composition/information on ingredients

Formula	C ₂₂ H ₂₇ FN ₄ O ₂ •C ₄ H ₆ O ₅
Molecular Weight	532.57 g/mol
Chemical nature	Monoconstituent substance
Synonyms	Sunitinib malate; Sutent;® 1H-Pyrrole-3-carboxamide, N-(2-(diethylamino)ethyl)-5-((Z)-(5-fluoro-1,2-dihydro-2-oxo-3H-indol-3-ylidene)methyl)-2,4-dimethyl-, (2S)-hydroxybutanedioate (1:1)

Chemical Name	CAS No	Weight %
Butanedioic acid, hydroxy-, (2S)-, compd. with N-(2-(diethylamino)ethyl)-5-((Z)-(5-fluoro-1,2-dihydro-2-oxo-3H-indol-3-ylidene)methyl)-2,4-dimethyl-1H-pyrrole-3-carboxamide (1:1)	341031-54-7	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

Fatigue, asthenia, fever, diarrhea, nausea, mucositis/stomatitis, vomiting, dyspepsia, abdominal pain, constipation, hypertension, peripheral edema, rash, hand-foot syndrome, skin discoloration, dry skin, hair color changes, altered taste, headache, back pain, arthralgia, extremity pain, cough, dyspnea, anorexia, and bleeding.

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 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 and collect in suitable container 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	Strong oxidizing agents.

SECTION 8. Exposure controls/personal protection

Control parameters

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

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
Appearance	Powder
Odor	No information available
Color	yellow-orange
Odor Threshold	No information available
pH	No information available
Melting point/freezing point	198-200 °C
Initial boiling point and boiling range	No information available
Flash point	No information available.
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	No information available.
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.
Explosive properties	No information available
Oxidizing properties	No information available
Molecular Weight	532.57 g/mol
VOC content	No information available
Viscosity	No information available.
Density	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

Protect from light and heat.

Incompatible Materials

Strong oxidizing agents.

Hazardous Decomposition Products

None known based on information supplied.

SECTION 11. Toxicological information

Information on likely routes of exposure

Inhalation	Inhalation of particulates may cause mechanical irritation to upper respiratory tract.
Eye contact	Contact with eyes may cause mechanical irritation.
Skin contact	Contact with skin may cause mild irritation.
Ingestion	Target Organ Effects. Reproductive Toxicity.

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	Fatigue, asthenia, fever, diarrhea, nausea, mucositis/stomatitis, vomiting, dyspepsia, abdominal pain, constipation, hypertension, peripheral edema, rash, hand-foot syndrome, skin discoloration, dry skin, hair color changes, altered taste, headache, back pain, arthralgia, extremity pain, cough, dyspnea, anorexia, and bleeding.
Sensitization	No information available.
Mutagenic effects	Not mutagenic in AMES Test. Negative in an in vivo rat micronucleus test. Negative in the chromosomal aberration 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. In rasH2 transgenic mice gastroduodenal carcinomas and/or gastric mucosal hyperplasia, as well as an increased incidence of background hemangiosarcomas were observed at doses of =25 mg/kg/day following daily dose administration of sunitinib in studies of 1 or 6 months duration. No proliferative changes were observed in rasH2 transgenic mice at 8 mg/kg/day. In a 2-year Sprague-Dawley rat carcinogenicity study, administration of sunitinib in 28-day cycles followed by 7-day dose-free periods resulted in findings of duodenal carcinoma at doses as low as 1 mg/kg/day. At the high dose of 3 mg/kg/day the incidence of duodenal tumors was increased and was accompanied by findings of gastric mucous cell hyperplasia and by an increased incidence of pheochromocytoma and hyperplasia of the adrenal.

Reproductive toxicity

This material is classified as a Pregnancy Category D: Positive evidence of risk. Effects on the female reproductive system were identified in a 3-month repeat dose monkey study (2, 6, 12 mg/kg/day), where ovarian changes were noted at 12 mg/kg/day while uterine changes (endometrial atrophy) were noted at 2 mg/kg/day. With the addition of vaginal atrophy, the uterine and ovarian effects were reproduced at 6 mg/kg/day in the 9-month monkey study. 1.5 mg/kg/day represents a no effect level in monkeys administered sunitinib for 9 months. In female rats, no fertility effects were observed at doses of 5.0 mg/kg/day administered for 21 days up to gestational day 7, however significant embryoletality was observed at the 5.0 mg/kg dose. No reproductive effects were observed in male rats dosed (1, 3 or 10 mg/kg/day) for 58 days prior to mating with untreated females. Fertility, copulation, conception indices, and sperm evaluation (morphology, concentration, and motility) were unaffected by sunitinib at doses 10 mg/kg/day.

**STOT - single exposure
STOT - repeated exposure**

No information available.
Hepatotoxicity (including liver failure), cardiac toxicity and cardiac failure (left ventricular ejection fraction declines to below the lower limit of normal, prolonged QT intervals, torsade de pointes), osteonecrosis of the jaw, thyroid dysfunction, hypoglycemia and Stevens-Johnson syndrome or toxic epidermal necrolysis.

**Neurological effects
Aspiration Hazard**

No information available.
No information available.

SECTION 12. Ecological information

Ecotoxicity

Product does not present an aquatic toxicity hazard based on known or supplied information.

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

Butanedioic acid, hydroxy-, (2S)-, compd. with N-(2-(diethylamino)ethyl)-5-((Z)-(5-fluoro-1,2-dihydro-2-oxo-3H-indol-3-ylidene)methyl)-2,4-dimethyl-1H-pyrrole-3-carboxamide (1:1)	Not Listed	Not Listed	Not Listed	Not Listed
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Canadian Workplace Hazardous Materials Information System (WHMIS) Classification

	Class D2A - Very Toxic Material at >= 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