

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

**Issuing Date:** 2015-01-15

**Revision Date:** 2018-03-26

**Version:** 3

## SECTION 1. Identification

### Product identifier

**Product No** 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.

### 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)

<b>Reproductive toxicity</b>	Category 1B
<b>Specific target organ toxicity - repeated exposure (STOT RE)</b>	Category 1

### GHS Label elements, including precautionary statements



**Signal Word**  
 Danger

### **Hazard statement(s)**

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. 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. 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**

<b>Formula</b>	C <sub>22</sub> H <sub>27</sub> FN <sub>4</sub> O <sub>2</sub> •C <sub>4</sub> H <sub>6</sub> O <sub>5</sub>
<b>Molecular Weight</b>	532.57 g/mol
<b>Chemical nature</b>	Monoconstituent substance
<b>Synonyms</b>	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)

<b>Chemical Name</b>	<b>CAS No</b>	<b>Weight %</b>
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**

<b>Eye contact</b>	Rinse thoroughly with plenty of water, also under the eyelids. Keep eye wide open while rinsing.
<b>Skin contact</b>	Immediate medical attention is required. Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.
<b>Inhalation</b>	Immediate medical attention is required. Move to fresh air. If not breathing, give artificial respiration.
<b>Ingestion</b>	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. Vomiting. Abdominal pain. Constipation. hypertension. Peripheral edema. rash. Dry skin. Headache. back pain. Arthralgia. Shortness of breath or cough. dyspnea. Anorexia. mucositis. indigestion. hand-foot syndrome. skin discoloration. altered taste. extremity pain. Bleeding.

### **Indication of any immediate medical attention and special treatment needed**

Treat symptomatically.

### **Advice for emergency responders**

<b>General advice</b>	Immediate medical attention is required. Show this safety data sheet to the doctor in attendance.
<b>Protection of first-aiders</b>	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, 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** Strong oxidizing agents.

**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.

<b>Eye/face protection</b>	Tightly fitting safety goggles
<b>Skin and body protection</b>	Wear protective gloves/clothing.
<b>Respiratory protection</b>	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.
<b>Hygiene measures</b>	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

<b>Physical state</b>	Solid	<b>Color</b>	yellow-orange
<b>Appearance</b>	Powder	<b>Odor Threshold</b>	No information available
<b>Odor</b>	No information available		
<b>Property</b>	<b>Values</b>	<b>Remarks</b>	<b>Method</b>
<b>pH</b>	No information available		
<b>Melting point/freezing point</b>	198-200 °C		
<b>Initial boiling point and boiling range</b>			
<b>Flash point</b>		-	
<b>Evaporation rate</b>	No information available		
<b>Flammability (solid, gas)</b>	No information available		
<b>Upper flammability limit</b>	No information available		
<b>Lower flammability limit</b>	No information available		
<b>Vapor pressure</b>	No information available		
<b>Vapor density</b>	No information available		
<b>Relative density</b>	No information available		
<b>Solubility</b>	No information available.		
<b>Solubility in other solvents</b>	No information available.		
<b>Partition coefficient: n-octanol/water</b>	No information available		
<b>Autoignition temperature</b>	No information available		
<b>Decomposition temperature</b>	No information available		
<b>Viscosity</b>	No information available		
<b>Viscosity, dynamic</b>	No information available		
<b>Explosive properties</b>	No information available		
<b>Oxidizing properties</b>	No information available		
<b>Other information</b>			
<b>Softening point</b>	No information available		
<b>Molecular Weight</b>	532.57 g/mol		
<b>VOC content</b>	No information available		
<b>Density</b>	No information available.		
<b>Bulk Density VALUE</b>	No information available.		

## SECTION 10. Stability and reactivity

### Reactivity

No information available.

### Chemical stability

Stable under recommended storage conditions.

**Possibility of hazardous reactions**

<b>Hazardous reactions</b>	None under normal processing.
<b>Hazardous polymerization</b>	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.

<b>SECTION 11. Toxicological information</b>
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**Information on likely routes of exposure**

<b>Inhalation</b>	May cause irritation of respiratory tract.
<b>Eye contact</b>	Contact with eyes may cause irritation.
<b>Skin contact</b>	May cause irritation.
<b>Ingestion</b>	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**

<b>Symptoms</b>	Fatigue. Asthenia. Fever. Diarrhea. Nausea. Vomiting. Abdominal pain. Constipation. hypertension. Peripheral edema. rash. Dry skin. Headache. back pain. Arthralgia. Shortness of breath or cough. dyspnea. Anorexia. mucositis. indigestion. hand-foot syndrome. skin discoloration. altered taste. extremity pain. Bleeding.
<b>Sensitization</b>	No information available.
<b>Mutagenic effects</b>	Not mutagenic in AMES Test. Negative in an in vivo rat micronucleus test. Negative in the chromosomal aberration assay.
<b>Carcinogenicity</b>	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.
<b>Reproductive toxicity</b>	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

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

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 embryolethality 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.

No information available.

**Neurological effects**  
**Aspiration Hazard**

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.

No information available.

No information available.

## SECTION 12. Ecological information

### Ecotoxicity

**Persistence and degradability**  
**Bioaccumulation**  
**Mobility**

No information available.

No information available.

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

### Canadian Workplace Hazardous Materials Information System (WHMIS) Classification

Class D2A - Very Toxic Material at  $\geq 0.1\%$ **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.

<b>SECTION 16. Other information</b>
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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