



**SAFETY DATA SHEET (SDS):** According to the REACH Regulation (EC) No. 1907/2006  
**Issuing Date:** 2015-01-07 **Revision Date:** 2015-01-08

**Version:** 2

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

**Product number** 9084  
**Product name** Imatinib  
**Reach registration number** This substance/mixture contains only ingredients which have been registered, or are exempt from registration, according to Regulation (EC) No. 1907/2006.

### Contains

Chemical Name	Index No.	CAS No
Benzamide, 4-((4-methyl-1-piperazinyl)methyl)-N-(4-methyl-3- ((4-(3-pyridinyl)-2-pyrimidinyl)amino)phenyl)-, monomethanesulfonate (90 - 100%)	Not Listed	220127-57-1

<b>Formula</b>	C <sub>29</sub> H <sub>31</sub> N <sub>7</sub> O•CH <sub>4</sub> SO <sub>3</sub>
<b>Molecular Weight</b>	589.71 g/mol
<b>Other means of identification</b>	9084S

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**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.

### 1.3. Details of the supplier of the safety data sheet

Importer	Manufacturer
Cell Signaling Technology Europe B.V. Schuttersveld 2 2316 ZA Leiden The Netherlands TEL: +31 71 562 1060 FAX: +31 71 586 1065	Cell Signaling Technology, Inc. 3 Trask Lane Danvers, MA 01923 United States TEL: +1 978 867 2300 FAX: +1 978 867 2400

<b>Website</b>	www.cellsignal.com
<b>E-mail Address</b>	info@cellsignal.eu

### 1.4. Emergency telephone number

**Europe** 112

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

<b>Carcinogenicity</b>	Category 2 - (H351)
<b>Reproductive toxicity</b>	Category 1B - (H360Df)
<b>Effects on or via lactation</b>	Effects on or via lactation - (H362)
<b>Specific target organ toxicity - repeated exposure (STOT RE)</b>	Category 1 - (H372)

Chronic aquatic toxicity	Category 3 - (H412)
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For the full text of the H-phrases & EUH-phrases mentioned in this Section, see Section 16

#### Directives 67/548/EEC and 1999/45/EC

**Symbol(s)** T - Toxic  
**R-phrases(s)** Carc. cat. 3;R40 - Repr. cat. 2;R61 - Repr. cat. 3;R62 - T;R48/25 - R43 - R52/53

For the full text of the R-phrases mentioned in this Section, see Section 16

#### 2.2. Label elements



#### Signal word

Danger

#### Hazard statement(s)

H351 - Suspected of causing cancer if swallowed  
 H360Df - May damage the unborn child. Suspected of damaging fertility  
 H362 - May cause harm to breast-fed children  
 H372 - Causes damage to organs through prolonged or repeated exposure  
 H412 - Harmful to aquatic life with long lasting effects

#### Precautionary statement(s)

P201 - Obtain special instructions before use  
 P202 - Do not handle until all safety precautions have been read and understood  
 P260 - Do not breathe dust/fume/gas/mist/vapors/spray  
 P263 - Avoid contact during pregnancy/while nursing  
 P281 - Use personal protective equipment as required  
 P308 + P313 - IF exposed or concerned: Get medical advice/attention

#### 2.3. Other hazards

None required for material as supplied

### SECTION 3: Composition/information on ingredients

#### 3.1 Substances

**Chemical nature** Monoconstituent substance  
**Formula** C<sub>29</sub>H<sub>31</sub>N<sub>7</sub>O•CH<sub>4</sub>SO<sub>3</sub>  
**Molecular Weight** 589.71 g/mol  
**Synonyms** Imatinib Mesylate;  
 Gleevec;  
 4-[(4-Methyl-1-piperazinyl)methyl]-N- [4-methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-13-phenyl]benzamide methanesulfonate

Chemical Name	EC No	CAS No	Weight %	Classification (67/548)	Classification (1272/2008)	REACH Registration Number

Benzamide, 4-((4-methyl-1-piperazinyl)methyl)-N-(4-methyl-3-((4-(3-pyridinyl)-2-pyrimidinyl)amino)phenyl)-, monomethanesulfonate	-	220127-57-1	100	T;48/25-R61 Xn;R40-R62 R52/53 R43	Carc. 2 (H351) Repr. 1B (H360Df) Lact. (H362) STOT RE 1 (H372) Aquatic Chronic 3 (H412)	no data available
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For the full text of the R-phrases mentioned in this Section, see Section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

<b>General advice</b>	Use first aid treatment according to the nature of the injury. When symptoms persist or in all cases of doubt seek medical advice.
<b>Inhalation</b>	Move to fresh air.
<b>Skin contact</b>	Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Ingestion</b>	Clean mouth with water and afterwards drink plenty of water.

### 4.2. Most important symptoms and effects, both acute and delayed

<b>Main symptoms</b>	The most frequently reported drug-related adverse events were nausea, vomiting, diarrhea, edema, and muscle cramps. A variety of adverse events represent local or general fluid retention including pleural effusion, ascites, pulmonary edema and rapid weight gain with or without superficial edema.
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### 4.3. Indication of any immediate medical attention and special treatment needed

<b>Notes to physician</b>	Treat symptomatically.
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## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Unsuitable Extinguishing Media</b>	No information available.

### 5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors.

### 5.3. Advice for firefighters

Wear self-contained breathing apparatus and protective suit. Use personal protective equipment.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

<b>For non-emergency personnel</b>	Evacuate personnel to safe areas. Ensure adequate ventilation.
<b>For emergency responders</b>	Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

Do not flush into surface water or sanitary sewer system.

### 6.3. Methods and material for containment and cleaning up

**Methods for containment  
Methods for cleaning up**

Prevent further leakage or spillage if safe to do so.  
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.

**6.4. Reference to other sections**

See Section 8 and 13 for further information.

**SECTION 7: Handling and storage****7.1. Precautions for safe handling**

Use according to package label instructions. Handle in accordance with good industrial hygiene and safety practice.

**7.2. Conditions for safe storage, including any incompatibilities**

Keep container tightly closed in a dry and well-ventilated place.

**7.3. Specific end use(s)**

Use as laboratory reagent (PROC15).

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters**

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

**8.2. Exposure controls****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**

Safety glasses with side-shields.

**Skin protection****Hand protection**

Impervious gloves.

**Other**

Wear suitable protective clothing.

**Respiratory protection**

In case of inadequate ventilation wear respiratory protection.

**Environmental Exposure Controls**

No information available.

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

<b>Physical state</b>	Solid
<b>Appearance</b>	Crystalline powder
<b>Color</b>	Off-white to pale yellow
<b>Odor</b>	No information available
<b>Odor Threshold</b>	No information available

**Property****Values****Remarks • Method**

pH		No information available
Melting point/freezing point	203-224 °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	Partly soluble	200 mg/ml Miscible
Partition coefficient: n-octanol/water		No information available
Autoignition temperature		No information available
Decomposition temperature		No information available.
Viscosity		No information available
Explosive properties		No information available
Oxidizing properties		No information available

**9.2. Other information**

Softening point	No information available
Molecular Weight	589.71 g/mol
Solubility in other solvents	Soluble in dimethyl sulfoxide (DMSO) @ 100 mg/mL
VOC content	No information available
Density	No information available.

## SECTION 10: Stability and reactivity

**10.1. Reactivity**

No information available.

**10.2. Chemical stability**

Stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

**10.3. Possibility of hazardous reactions**

<b>Hazardous polymerization</b>	Hazardous polymerization does not occur.
<b>Hazardous reactions</b>	None under normal processing.

**10.4. Conditions to avoid**

None known based on information supplied.

**10.5. Incompatible materials**

No information available.

**10.6. Hazardous decomposition products**

None under normal use.

## SECTION 11: Toxicological information

**11.1. 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.

**Information on likely routes of exposure**

<b>Inhalation</b>	Inhalation of particulates may cause mechanical irritation to upper respiratory tract.
<b>Eye contact</b>	Contact with eyes may cause mechanical irritation.
<b>Skin contact</b>	Contact with skin may cause mechanical irritation.
<b>Ingestion</b>	May be harmful if swallowed. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.
<b>Symptoms</b>	The most frequently reported drug-related adverse events were nausea, vomiting, diarrhea, edema, and muscle cramps. A variety of adverse events represent local or general fluid retention including pleural effusion, ascites, pulmonary edema and rapid weight gain with or without superficial edema.
<b>Skin corrosion/irritation</b>	Not irritating to skin.
<b>Serious eye damage/eye irritation</b>	No information available.
<b>Sensitization</b>	Did not cause sensitization on laboratory animals.
<b>Mutagenic effects</b>	The weight of evidence demonstrates that this material is not genotoxic: Negative in an in vivo rat micronucleus test. Negative in the Ames test. Caused chromosomal aberrations in vitro in Chinese hamster ovary (CHO) cells.
<b>Carcinogenic effects</b>	In a 2-year feed study in rats, there was evidence for a carcinogenic effect of imatinib mesylate in the kidneys, urinary bladder, preputial gland, and clitoral gland. The no observed adverse effect levels (NOAEL) for the various target organs with neoplastic lesions could be established as follows: 30 mg/kg/day for kidney and urinary bladder and 15 mg/kg/day for preputial and clitoral gland.
<b>Reproductive toxicity</b>	This material is classified as a Pregnancy Category D: Positive evidence of risk. In a study of fertility, in male rats dosed for 70 days prior to mating, testicular and epididymal weights and percent motile sperm were decreased at 60 mg/kg. This was not seen at doses =20 mg/kg. In female rats dosed with imatinib mesylate at 45 mg/kg from gestational day 6 until the end of lactation, red vaginal discharge was noted on either gestational day 14 or 15. In lactating female rats administered 100 mg/kg, imatinib and its metabolites were extensively excreted in milk. Concentration in milk was approximately three-fold higher than in plasma. It is estimated that approximately 1.5% of a maternal dose is excreted into milk, which is equivalent to a dose to the infant of 30% the maternal dose per unit body weight. Male and female rats were exposed in utero to a maternal imatinib mesylate dose of 45 mg/kg from day 6 of gestation and through milk during the lactation period. These animals then received no imatinib exposure for nearly 2 months. Body weights were reduced from birth until terminal sacrifice in these rats. Although fertility was not affected, fetal loss was seen when these male and female animals were then mated.
<b>Teratogenicity</b>	Imatinib mesylate was teratogenic in rats when administered during organogenesis at doses =100 mg/kg. Teratogenic effects included exencephaly or encephalocele, absent/reduced frontal and absent parietal bones. Female rats administered doses = 45 mg/kg experienced significant post-implantation loss as evidenced by either early fetal resorption or stillbirths, nonviable pups and early pup mortality between postpartum days 0 and 4. At doses higher than 100 mg/kg, total fetal loss was noted in all animals. Fetal loss was not seen at doses =30 mg/kg.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	Severe liver toxicity was observed in dogs treated for 2 weeks, with elevated liver enzymes, hepatocellular necrosis, bile duct necrosis, and bile duct hyperplasia. Renal toxicity was observed in monkeys treated for 2 weeks, with focal mineralization and dilation of the renal tubules and tubular nephrosis. Increased BUN and creatinine were observed in several of these animals. An increased rate of opportunistic infections was observed with chronic imatinib treatment in laboratory animal studies. In a 39-week monkey study, treatment with imatinib resulted in worsening of normally suppressed malarial infections in these animals. Lymphopenia was observed in animals (as in humans).
<b>Target Organ Effects</b>	Liver, Kidney, Immune system, Gastrointestinal tract (GI).
<b>Aspiration Hazard</b>	No information available.
<b>Other information</b>	No information available.

**SECTION 12: Ecological information****12.1. Toxicity**

Harmful to aquatic life with long lasting effects

Chemical Name	Toxicity to algae	Toxicity to fish	Toxicity to daphnia and other aquatic invertebrates
Benzamide, 4-((4-methyl-1-piperazinyl)methyl)-N-(4-methyl-3-((4-(3-pyridinyl)-2-pyrimidinyl)amino)phenyl)-, monomethanesulfonate	NOEC 0.96 mg/L (Selenastrum capricornutum) 72 h	LC50 82 mg/L (Cyprinus carpio) 96 h	EC50 80 mg/L (Daphnia magna) 48 h

**Unknown Aquatic Toxicity** 100% of the mixture consists of components(s) of unknown hazards to the aquatic environment.

### 12.2. Persistence and degradability

Not readily biodegradable. 9-12% 28 day period.

### 12.3. Bioaccumulative potential

**Bioaccumulation** Not likely to bioaccumulate.  
**Bioconcentration factor (BCF)** No information available.

Chemical Name	Octanol-Water Partition Coefficient
Benzamide, 4-((4-methyl-1-piperazinyl)methyl)-N-(4-methyl-3-((4-(3-pyridinyl)-2-pyrimidinyl)amino)phenyl)-, monomethanesulfonate	< 3.0

### 12.4. Mobility in soil

Will likely be mobile in the environment due to its water solubility.

### 12.5. Results of PBT and vPvB assessment

No information available.

### 12.6. Other adverse effects

No information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

**Waste from residues / unused products** Dispose of in accordance with local regulations.  
**Contaminated packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal.  
**Other information** Waste codes should be assigned by the user based on the application for which the product was used.

## SECTION 14: Transport information

### IMDG/IMO

**14.1 UN number** Not regulated  
**14.2 UN proper shipping name** Not regulated  
**14.3 Transport hazard class(es)** Not regulated  
**14.4 Packing group** Not regulated  
**14.5 Environmental hazards** None  
**14.6 Special precautions for user** None  
**14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not regulated

**ADR/RID**

14.1 UN number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	None
14.6 Special precautions for user	None

**IATA**

14.1 UN number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	None
14.6 Special precautions for user	None

<b>SECTION 15: Regulatory information</b>
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**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****Candidate List of Substances of Very High Concern for Authorisation Information**

This product does not contain Substances of Very High Concern (SVHC).

**SEVESO Directive Information**

This product does not contain substances identified in the SEVESO Directive.

**International inventories**

TSCA 8(b)	-
DSL/NDSL	-
EINECS/ELINCS	-
ENCS	-
IECSC	-
KECL	-
PICCS	-
AICS	-

**International inventories legend**

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

**15.2. Chemical safety assessment**

A chemical safety assessment has not been completed for this substance/mixture.

<b>SECTION 16: Other information</b>
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**Full text of R-Phrases referred to under Sections 2 and 3**

R43 - May cause sensitization by skin contact  
 R61 - May cause harm to the unborn child  
 R40 - Limited evidence of a carcinogenic effect  
 R62 - Possible risk of impaired fertility



R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment  
R48/25 - Also toxic: danger of serious damage to health by prolonged exposure if swallowed

**Full text of H-Statements referred to under Sections 2 and 3**

This substance/mixture does not meet the criteria for classification in accordance with Regulation (EC) No. 1272/2008

**Classification procedure:** Calculation method. Bridging principle "Dilution".  
**Issuing Date:** 2015-01-07  
**Revision Date:** 2015-01-08  
**Reason for revision:** not applicable.

**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.