**Safety Data Sheet (SDS)** According to the REACH Regulation (EC) No. 1907/2006

**Issuing Date:** 2015-01-07 **Revision Date:** 2018-03-26 **Version:** 3

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

### 1.1. Product identifier

**Product No** 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**

**Formula** $C_{29}H_{31}N_7O \cdot CH_4SO_3$
**Molecular Weight** 589.71 g/mol

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

**Identified uses** For research use only

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

**Importer (Applicable in EU only)**
Cell Signaling Technology Europe B.V.
Schuttersveld 2
2316 ZA Leiden
The Netherlands
TEL: +31 (0)71 7200 200
FAX: +31 (0)71 891 0098

**Manufacturer**
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
**E-mail Address** info@cellsignal.eu

### 1.4. Emergency telephone number

**CHEMTREC** 24 hours a day, 7 days a week, 365 days a year
+1 703 527 3887 (INTERNATIONAL) +1 800 424 9300 (NORTH AMERICA)

**Europe** 112

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

**Regulation (EC) No. 1272/2008**

| | |
|---|---|
| **Carcinogenicity** | Category 2 - (H351) |
| **Reproductive toxicity** | Category 1B - (H360Df) |
| **Effects on or via lactation** | Effects on or via lactation - (H362) |
| **Specific target organ toxicity - repeated exposure (STOT RE)** | Category 1 - (H372) |
| **Chronic aquatic toxicity** | Category 3 - (H412) |

### 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
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P273 - Avoid release to the environment
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P405 - Store locked up
P501 - Dispose of contents/container to an approved waste disposal plant

### 2.3. Other hazards

*For the full text of the H-phrases & EUH-phrases mentioned in this Section, see Section 16*

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

**Synonyms** Imatinib Mesylate;
Gleevec;
4-[(4-Methyl-1-piperazinyl)methyl]-N- [4-methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-13 phenyl]benzamide methanesulfonate

**Formula** $C_{29}H_{31}N_7O \bullet CH_4SO_3$

**Chemical nature** Monoconstituent substance.

| Chemical Name | CAS No | Weight % | EC No | 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 | - | Carc. 2 (H351)<br>Repr. 1B (H360Df)<br>Lact. (H362)<br>STOT RE 1 (H372)<br>Aquatic Chronic 3 (H412) | no data available |

*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

**General advice** Use first aid treatment according to the nature of the injury. When symptoms persist or in all cases of doubt seek medical advice.

**Inhalation** Move to fresh air.

**Skin contact** Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.

**Eye contact** Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

**Ingestion** Clean mouth with water and afterwards drink plenty of water.

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

Nausea. Vomiting. Diarrhea. Edema. muscle pain. 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.

### 4.3. Indication of any immediate medical attention and special treatment needed

**Notes to physician** Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

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

**Unsuitable Extinguishing Media** 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

**For non-emergency personnel** Evacuate personnel to safe areas. Ensure adequate ventilation.

**For emergency responders** 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** 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.

### 6.4. Reference to other sections

See Sections 8 & 13 for additional information.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

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 a laboratory reagent.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

### 8.2. Exposure controls

**Appropriate engineering controls**
Showers, eyewash stations, and ventilation systems.

**Individual protection measures, such as personal protective equipment**

| | |
|---|---|
| **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

| | |
|---|---|
| **Physical state** | Solid |
| **Appearance** | Crystalline Powder |
| **Color** | Off-white - Yellow |
| **Odor** | No information available |
| **Odor Threshold** | 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 conditions.

**10.3. Possibility of hazardous reactions**

| | |
|---|---|
| **Hazardous polymerization** | Hazardous polymerization does not occur. |
| **Hazardous reactions** | 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 conditions.

## 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**

| | |
|---|---|
| **Inhalation** | May cause irritation of respiratory tract. |
| **Eye contact** | Contact with eyes may cause irritation. |
| **Skin contact** | May cause irritation. |
| **Ingestion** | May be harmful if swallowed. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. |
| **Symptoms** | Nausea. Vomiting. Diarrhea. Edema. muscle pain. 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. |
| **Skin corrosion/irritation** | not applicable. |

| | |
|---|---|
| **Serious eye damage/eye irritation** | No information available. |
| **Sensitization** | Did not cause sensitization on laboratory animals. |
| **Mutagenic effects** | 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. |
| **Carcinogenic effects** | 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. |
| **Reproductive toxicity** | 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. |
| **Teratogenicity** | 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. |
| **STOT - single exposure** | No information available. |
| **STOT - repeated exposure** | 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). |
| **Target Organ Effects** | Liver, Kidney, Immune system, Gastrointestinal tract (GI). |
| **Aspiration Hazard** | No information available. |
| **Other information** | 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 | N0EC 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 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

## SECTION 15: Regulatory information

**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

**Candidate List of Substances of Very High Concern for Authorization 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**

For this substance a chemical safety assessment has not been carried out

## SECTION 16: Other information

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

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

**Classification procedure:** Expert judgment and weight of evidence determination.
**Issuing Date:** 2015-01-07
**Revision Date:** 2018-03-26

**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.**