



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision Date 24-Nov-2022

Revision Number 3

72532 72534 - Imatinib (Mesylate)

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Document Number DX21125
Product Name Imatinib (Mesylate)
Synonyms CGP57148B; Gleevec; Glivec; STI-571;
Pure substance/mixture Substance

Contains methanesulfonic acid; 4-[(4-methylpiperazin-1-yl)methyl]-N-[4-methyl-3-[(4-pyridin-3-ylpyrimidin-2-yl)amino]phenyl]benzamide

Molecular weight 589.7

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

Recommended Use Laboratory chemicals
Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Manufacturer

STEMCELL Technologies SARL
40 Rue des Berges, Miniparc Polytec, Bâtiment Sirocco, 38000 Grenoble, France
+33 (0) 4 76 04 75 30
STEMCELL Technologies Germany GmbH
Stolberger Str. 200, 50933, Köln, Germany
+33 (0) 4 76 04 75 30
STEMCELL Technologies UK Ltd.
Building 7100, Cambridge Research Park, Beach Drive, Waterbeach, Cambridge, UK, CB25 9TL
+33 (0) 4 76 04 75 30

For further information, please contact

1.4. Emergency telephone number

Emergency Telephone No information available

Emergency Telephone - \$45 - (EC)1272/2008
Europe 112

Section 2: HAZARDS IDENTIFICATION



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2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute toxicity - Oral	Category 4 - (H302)
Acute toxicity - Dermal	Category 4 - (H312)
Germ cell mutagenicity	Category 2 - (H341)
Carcinogenicity	Category 2 - (H351)
Reproductive toxicity	Category 1A - (H360D)
Effects on or via lactation	Yes - (H362)
Specific target organ toxicity (repeated exposure)	Category 2 - (H373)
Chronic aquatic toxicity	Category 2 - (H411)

2.2. Label elements

Contains methanesulfonic acid; 4-[(4-methylpiperazin-1-yl)methyl]-N-[4-methyl-3-[(4-pyridin-3-ylpyrimidin-2-yl)amino]phenyl]benzamide



Signal word

Danger

Hazard statements

Hazard statements

- H302 - Harmful if swallowed
- H312 - Harmful in contact with skin
- H341 - Suspected of causing genetic defects
- H351 - Suspected of causing cancer
- H360D - May damage the unborn child
- H362 - May cause harm to breast-fed children
- H373 - May cause damage to organs through prolonged or repeated exposure
- H411 - Toxic to aquatic life with long lasting effects
- H303 - May be harmful if swallowed
- H313 - May be harmful in contact with skin

Precautionary Statements - EU (§28, 1272/2008)

- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P321 - Specific treatment (see supplemental instructions on the administration of antidotes on this label)
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P201 - Obtain special instructions before use
- P202 - Do not handle until all safety precautions have been read and understood
- P308 + P313 - IF exposed or concerned: Get medical advice/attention
- P260 - Do not breathe dust/fume/gas/mist/vapors/spray
- P263 - Avoid contact during pregnancy/while nursing
- P314 - Get medical advice/attention if you feel unwell
- P501 - Dispose of contents/container to industrial incineration plant



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Additional information

This product requires tactile warnings if supplied to the general public

2.3. Other hazards

No information available

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Synonyms

Chemical name	EC No.	CAS No.	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
methanesulfonic acid; 4-[(4-methylpiperazin-1-yl)methyl]-N-[4-methyl-3-[(4-pyridin-3-ylpyrimidin-2-yl)amino]phenyl]benzamide	-	220127-57-1	100	Muta. 2 (H341) Carc. 2 (H351) Repr. 1 (H360) Repr. 1B (H360D) STOT RE 2 (H373) Aquatic Chronic 2 (H411) Acute Tox. 4 (H302) Acute Tox. 4 (H312) Aquatic Acute 2 (H401)	No data available

Full text of H- and EUH-phrases: see section 16

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

General advice	IF exposed or concerned: Get medical advice/attention. Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash off immediately with plenty of water for at least 15 minutes. If symptoms persist, call a physician.
Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.



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Self-protection of the first aider Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Wear personal protective clothing (see section 8).

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

Symptoms No information available.

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

Note to physicians Treat symptomatically.

Section 5: FIRE-FIGHTING 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

Specific hazards arising from the chemical No information available.

Hazardous combustion products Carbon dioxide (CO₂). Carbon monoxide. Nitrogen oxides (NO_x). Oxides of sulfur.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas.

Other Information Refer to protective measures listed in Sections 7 and 8.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions



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

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 Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Handle in accordance with good industrial hygiene and safety practice. Ensure adequate ventilation.

General hygiene considerations Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep out of the reach of children. Store in accordance with information listed on the Product Information Sheet (PIS).

7.3. Specific end use(s)

Identified Uses

Risk Management Methods (RMM) The information required is contained in this Material Safety Data Sheet.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

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



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Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Hand protection Wear suitable gloves.

Skin and body protection Long sleeved clothing. Wear suitable protective clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

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
Color No information available
Odor No data available.
Odor threshold No data available

Property	Values	Remarks • Method
pH	No data available	None known
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	Product is not flammable.	



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Flammability Limit in Air		None known
Upper flammability limit:	No data available	
Lower flammability limit:	No data available	
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Relative density	No data available	None known
Water solubility	No data available	None known
Solubility(ies)	~2 mg/mL in PBS (pH 7.2); ~0.2 mg/mL in EtOH; ~14 mg/mL in DMSO; ~10 mg/mL in DMF;	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive properties	No information available	
Oxidizing properties	No information available	

9.2. Other information

Softening point	No information available
Molecular weight	589.7
Molecular formula	C ₂₉ H ₃₁ N ₇ O · CH ₄ SO ₃
VOC Content (%)	No information available
Liquid Density	No information available
Bulk density	No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity	No information available.
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10.2. Chemical stability

Stability	Stable under recommended transport or storage conditions.
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Explosion data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions	None under normal processing.
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10.4. Conditions to avoid



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Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials Strong oxidizing agents.

10.6. Hazardous decomposition products

Hazardous decomposition products Carbon dioxide (CO₂). Carbon monoxide. Nitrogen oxides (NO_x). Sulfur oxides.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Information on likely routes of exposure

Product Information

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	May be harmful if absorbed through the skin. Harmful in contact with skin. (based on components).
Ingestion	Specific test data for the substance or mixture is not available. Harmful if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Numerical measures of toxicity

Acute toxicity

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral)	500.00 mg/kg
ATEmix (dermal)	1,100.00 mg/kg

Unknown acute toxicity 100 % of the mixture consists of ingredient(s) of unknown toxicity.
0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.
0 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).
100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor).



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100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

Product Information

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

Skin corrosion/irritation No information available.

Product Information

Serious eye damage/eye irritation No information available.

Product Information

Respiratory or skin sensitization No information available.

Product Information

Germ cell mutagenicity Classification based on data available for ingredients. Contains a known or suspected mutagen.

Product Information

Carcinogenicity Classification based on data available for ingredients.

Product Information

Reproductive toxicity Classification based on data available for ingredients. May cause harm to breastfed babies.

Product Information

STOT - single exposure No information available.

Product Information

STOT - repeated exposure May cause damage to organs.

Product Information

Aspiration hazard No information available.

Section 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity Toxic to aquatic life with long lasting effects.

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.

Product Information

12.2. Persistence and degradability



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Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Other adverse effects

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. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

Section 14: TRANSPORT INFORMATION

Note: When sold in quantities of less than or equal to 1 mL, or 1 g, with an Excepted Quantity Code of E1, E2, E4, or E5, this item meets the De Minimis Quantities exemption, per IATA 2.6.10. Therefore packaging does not have to be labeled as Dangerous Goods/Excepted Quantity.

IMDG

14.1 UN Number	UN3077
14.2 UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Imatinib (mesylate))
14.3 Transport hazard class(es)	9
14.4 Packing Group	III
14.5 Marine pollutant	Not applicable
14.6 Special Provisions	None



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14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code No information available

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 hazard	Not applicable
14.6 Special Provisions	None

ADR

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 hazard	Not applicable
14.6 Special Provisions	None

IATA

14.1 UN Number	UN3077
14.2 UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (Imatinib (mesylate))
14.3 Transport hazard class(es)	9 Miscellaneous dangerous substances and articles
14.4 Packing Group	III
14.5 Environmental hazard	Not applicable
14.6 Special Provisions	None

Section 15: REGULATORY INFORMATION

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

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable



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Dangerous substance category per Seveso Directive (2012/18/EU)

E2 - Hazardous to the Aquatic Environment in Category Chronic 2

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventories

TSCA	Does not comply
DSL/NDL	Does not comply
EINECS/ELINCS	Does not comply
ENCS	Does not comply
IECSC	Does not comply
KECL	Does not comply
PICCS	Does not comply
AICS	Does not comply

Legend:

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

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

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European 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

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

H302 - Harmful if swallowed

H312 - Harmful in contact with skin

H341 - Suspected of causing genetic defects

H351 - Suspected of causing cancer

H360 - May damage fertility or the unborn child

H360D - May damage the unborn child

H373 - May cause damage to organs through prolonged or repeated exposure

H401 - Toxic to aquatic life

H411 - Toxic to aquatic life with long lasting effects

Legend



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SVHC: Substances of Very High Concern for Authorization:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

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This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

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. STEMCELL Technologies Inc. shall not be held liable for any damage resulting from handling or from contact with the product.