



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 26-Apr-2023

Revision Number 1.1

100-0250 100-0251 - Eltrombopag

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

1.1. Product identifier

Document Number 10000007592

Product Name Eltrombopag

Synonym SB497115;
3'-[2-[(2Z)-1-(3,4-dimethylphenyl)-1,5-dihydro-3-methyl-5-oxo-4H-pyrazol-4-ylidene]hydrazinyl]-2'-hydroxy-[1,1'-biphenyl]-3-carboxylic acid

Pure substance/mixture Substance

Contains 3-[3-[[2-(3,4-dimethylphenyl)-5-methyl-3-oxo-1H-pyrazol-4-yl]diazanyl]-2-hydroxyphenyl]benzoic acid

Molecular weight 442.5

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

Recommended Use Laboratory chemical

Uses advised against

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

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

Europe 112

Section 2: HAZARDS IDENTIFICATION



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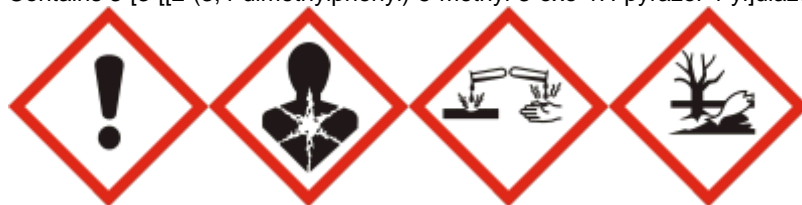
2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

| | |
|--|---------------------|
| Acute toxicity - Oral | Category 4 - (H302) |
| Serious eye damage/eye irritation | Category 1 - (H318) |
| Specific target organ toxicity (repeated exposure) | Category 2 - (H373) |
| Chronic aquatic toxicity | Category 1 - (H410) |

2.2. Label elements

Contains 3-[3-[[2-(3,4-dimethylphenyl)-5-methyl-3-oxo-1H-pyrazol-4-yl]diazenyl]-2-hydroxyphenyl]benzoic acid



Signal word

Danger

Hazard statements

Hazard statements

H302 - Harmful if swallowed

H318 - Causes serious eye damage

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

H410 - Very toxic to aquatic life with long lasting effects

H303 - May be harmful if swallowed

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

P280 - Wear eye protection/ face protection

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P310 - Immediately call a POISON CENTER or doctor

P260 - Do not breathe dust/fume/gas/mist/vapors/spray

P314 - Get medical advice/attention if you feel unwell

P501 - Dispose of contents/container to industrial incineration plant

Additional information

This product requires tactile warnings if supplied to the general public

2.3. Other hazards

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Synonym



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| Chemical name | EC No. | CAS No. | Weight-% | Classification according to Regulation (EC) No. 1272/2008 [CLP] | REACH Registration Number |
|---|--------|-------------|----------|--|---------------------------|
| 3-[3-[[2-(3,4-dimethylphenyl)-5-methyl-3-oxo-1H-pyrazol-4-yl]diazenyl]-2-hydroxyphenyl]benzoic acid | - | 496775-61-2 | 100 | Acute Tox. 4 (H302) Eye Dam. 1 (H318) STOT RE 2 (H373) Aquatic Chronic 1 (H410) | 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 | Show this safety data sheet to the doctor in attendance. Immediate medical attention is required. |
| Inhalation | Remove to fresh air. Get medical attention immediately if symptoms occur. |
| Eye contact | Get immediate medical advice/attention. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. |
| Skin contact | Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists. |
| 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. |
| Self-protection of the first aider | Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8). |

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

| | |
|----------|--------------------|
| Symptoms | Burning sensation. |
|----------|--------------------|

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 |
|------------------------------|--|



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surrounding environment.

Unsuitable Extinguishing Media

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical

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. Use personal protective equipment as required. Ensure adequate ventilation. 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

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



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Advice on safe handling

Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. 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.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions

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.

Derived No Effect Level (DNEL)

Predicted No Effect Concentration (PNEC)

8.2. Exposure controls

Personal protective equipment

Eye/face protection

Tight sealing safety goggles.

Hand protection

Wear suitable gloves.

Skin and body protection

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.



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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.

Environmental exposure controls

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

| | |
|----------------|--------------------|
| Physical state | Solid |
| Appearance | Crystalline |
| Color | |
| 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. | None known |
| 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) | DMF: 1 mg/mL; DMF:PBS (pH 7.2)(1:3): 0.25 mg/mL; DMSO:20 mg/mL; Ethanol: 0.1 mg/mL | 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 | | |

Oxidizing properties

9.2. Other information

| | |
|-------------------|---|
| Molecular weight | 442.5 |
| Molecular formula | C ₂₅ H ₂₂ N ₄ O ₄ |
| VOC Content (%) | |



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Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity

10.2. Chemical stability

Stability

Stable under recommended transport or storage conditions.

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.

Hazardous polymerization

Hazardous polymerization does not occur.

10.4. Conditions to avoid

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, carbon monoxide, nitrogen 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. Severely irritating to eyes. Causes serious eye damage. May cause burns. May cause irreversible damage to eyes.



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Skin contact

Specific test data for the substance or mixture is not available. May cause irritation.

Ingestion

Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Harmful if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms

Redness. Burning. May cause blindness.

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

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.

100 % 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).

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

May cause skin irritation.

Product Information

Serious eye damage/eye irritation

Classification based on data available for ingredients. Causes burns. Risk of serious damage to eyes.

Product Information

Respiratory or skin sensitization

Product Information

Germ cell mutagenicity

Product Information

Carcinogenicity

Product Information



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Reproductive toxicity

Product Information

STOT - single exposure

Product Information

STOT - repeated exposure

May cause damage to organs.

Product Information

Aspiration hazard

Section 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity

Very 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

Persistence and degradability

12.3. Bioaccumulative potential

Bioaccumulation

12.4. Mobility in soil

Mobility in soil

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

12.6. Other adverse effects

Other adverse effects

Section 13: DISPOSAL CONSIDERATIONS



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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. (Eltrombopag)
 14.3 Transport hazard class(es) 9 Miscellaneous dangerous substances and articles
 14.4 Packing Group III
 14.5 Marine pollutant
 14.6 Special Provisions None
 14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

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
 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
 14.6 Special Provisions None

IATA

14.1 UN Number UN3077
 14.2 UN proper shipping name Environmentally hazardous substance, solid, n.o.s.(Eltrombopag)
 14.3 Transport hazard class(es) 9 Miscellaneous dangerous substances and articles
 14.4 Packing Group III



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14.5 Environmental hazard

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

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

E1 - Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

International Inventories

| | |
|---------------|-----------------|
| TSCA | Does not comply |
| DSL/NDSL | 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/NDSL - 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



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AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report

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

H318 - Causes serious eye damage

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

H410 - Very toxic to aquatic life with long lasting effects

Legend

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

Revision Date

26-Apr-2023

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.