

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Sotatercept Solid Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 04/14/2025  |
| 4.0     | 06/17/2025     | 10607425-00010 | Date of first issue: 02/14/2022 |

### SECTION 1. IDENTIFICATION

Product name : Sotatercept Solid Formulation  
Other means of identification : No data available

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use


Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Reproductive toxicity : Category 1B  
Specific target organ toxicity : Category 1 (Blood, Immune system, Liver)  
- repeated exposure

#### GHS label elements

|                          |  |
|--------------------------|--|
| Hazard pictograms        | :   |
| Signal Word              | : Danger   |
| Hazard Statements        | : H360FD May damage fertility. May damage the unborn child.<br>H372 Causes damage to organs (Blood, Immune system, Liver) through prolonged or repeated exposure.  |
| Precautionary Statements | : <b>Prevention:</b><br>P201 Obtain special instructions before use.<br>P202 Do not handle until all safety precautions have been read and understood.<br>P260 Do not breathe dust.<br>P264 Wash skin thoroughly after handling.<br>P270 Do not eat, drink or smoke when using this product.<br>P280 Wear protective gloves, protective clothing, eye protection and face protection.<br><b>Response:</b><br>P308 + P313 IF exposed or concerned: Get medical attention. |

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### Storage:

P405 Store locked up.

### Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

### Other hazards

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

| Chemical name | Common Name/Synonym                                 | CAS-No.      | Concentration (% w/w) |
|---------------|---|--------------|-----------------------|
| Sucrose       | .alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl | 57-50-1      | $\geq 60 - < 80$ *    |
| Sotatercept   | No data available                                   | 1001080-50-7 | $\geq 30 - < 60$ *    |

\* Actual concentration or concentration range is withheld as a trade secret

## SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.  
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.

In case of eye contact : If in eyes, rinse well with water.  
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.  
May damage fertility. May damage the unborn child.  
Causes damage to organs through prolonged or repeated

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|                            |   |  |
|----------------------------|---|--|
| Protection of first-aiders | : | exposure.<br>First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8). |
| Notes to physician         | : | Treat symptomatically and supportively.  |

### SECTION 5. FIRE-FIGHTING MEASURES

|  |   |   |
|--|---|---|
| Suitable extinguishing media                   | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical  |
| Unsuitable extinguishing media                 | : | None known.   |
| Specific hazards during fire fighting          | : | Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.<br>Exposure to combustion products may be a hazard to health.                   |
| Hazardous combustion products                  | : | Carbon oxides<br>Metal oxides   |
| Specific extinguishing methods                 | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |

### SECTION 6. ACCIDENTAL RELEASE MEASURES

|   |   |   |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).  |
| Environmental precautions   | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained.   |
| Methods and materials for containment and cleaning up               | : | Sweep up or vacuum up spillage and collect in suitable container for disposal.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).<br>Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are |

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released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### SECTION 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe dust.  
Do not swallow.  
Avoid contact with eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.  
Store locked up.  
Keep tightly closed.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

| Components | CAS-No. | Value type<br>(Form of exposure) | Control parameters / Permissible concentration | Basis     |
|------------|---------|----------------------------------|--|-----------|
| Sucrose    | 57-50-1 | TWA                              | 10 mg/m <sup>3</sup>                           | CA AB OEL |
|            |         | TWA (Total                       | 10 mg/m <sup>3</sup>                           | CA BC OEL |

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|             |              |                                |                              |           |
|-------------|--------------|--------------------------------|------------------------------|-----------|
|             |              | dust)                          |                              |           |
|             |              | TWA (respirable dust fraction) | 3 mg/m <sup>3</sup>          | CA BC OEL |
|             |              | TWAEV                          | 10 mg/m <sup>3</sup>         | CA QC OEL |
|             |              | TWA                            | 10 mg/m <sup>3</sup>         | ACGIH     |
| Sotatercept | 1001080-50-7 | TWA                            | 20 µg/m <sup>3</sup> (OEB 3) | Internal  |
|             |              | Wipe limit                     | 200 µg/100 cm <sup>2</sup>   | Internal  |

**Engineering measures** : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

### Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

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|  |   |   |
|--|---|---|
| Appearance                                       | : | powder  |
| Color  | : | white to off-white  |
| Odor   | : | No data available   |
| Odor Threshold                                   | : | No data available   |
| pH   | : | No data available   |
| Melting point/freezing point                     | : | No data available   |
| Initial boiling point and boiling range          | : | No data available   |
| Flash point                                      | : | Not applicable  |
| Evaporation rate                                 | : | Not applicable  |
| Flammability (solid, gas)                        | : | May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids)                           | : | Not applicable  |
| Upper explosion limit / Upper flammability limit | : | No data available   |
| Lower explosion limit / Lower flammability limit | : | No data available   |
| Vapor pressure                                   | : | Not applicable  |
| Relative vapor density                           | : | Not applicable  |
| Relative density                                 | : | No data available   |
| Density  | : | No data available   |
| Solubility(ies)<br>Water solubility              | : | No data available   |
| Partition coefficient: n-octanol/water           | : | Not applicable  |
| Autoignition temperature                         | : | No data available   |
| Decomposition temperature                        | : | No data available   |
| Viscosity<br>Viscosity, kinematic                | : | Not applicable  |
| Explosive properties                             | : | Not explosive   |
| Oxidizing properties                             | : | The substance or mixture is not classified as oxidizing.                        |

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Molecular weight : 160 kg/mol

Particle characteristics  
Particle size : No data available

### SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

##### Sucrose:

Acute oral toxicity : LD50 (Rat): 29,700 mg/kg

##### Sotatercept:

Acute oral toxicity : Remarks: No data available

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : Remarks: No data available

#### Skin corrosion/irritation

Not classified based on available information.

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### Components:

#### Sotatercept:

||Remarks : No data available

#### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### Sotatercept:

||Remarks : No data available

#### Respiratory or skin sensitization

##### Skin sensitization

Not classified based on available information.

##### Respiratory sensitization

Not classified based on available information.

### Components:

#### Sotatercept:

||Remarks : No data available

#### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Sucrose:

||Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative

#### Sotatercept:

||Genotoxicity in vitro : Remarks: No data available

||Genotoxicity in vivo : Remarks: No data available

||Germ cell mutagenicity - Assessment : No data available

#### Carcinogenicity

Not classified based on available information.

### Components:

#### Sotatercept:

||Remarks : No data available

||Carcinogenicity - Assessment : No data available



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### Reproductive toxicity

May damage fertility. May damage the unborn child.

### Components:

#### Sotatercept:

|                                    |   |
|------------------------------------|---|
| Effects on fertility               | : <ul style="list-style-type: none"><li>Test Type: reproductive and developmental toxicity study</li><li>Species: Rat, male and female</li><li>Application Route: Subcutaneous</li><li>Fertility: LOAEL: 0.3 mg/kg body weight</li><li>Method: Study of Fertility and Early Embryonic Development to Implantation</li><li>Result: Reduced fertility, Increased resorptions., Increase of early resorptions., Effects on fertility., Postimplantation loss., alteration in sperm morphology</li></ul><br><ul style="list-style-type: none"><li>Test Type: Reproduction/Developmental toxicity screening test</li><li>Species: Rabbit, female</li><li>Application Route: Subcutaneous</li><li>General Toxicity Parent: NOAEL: 5 mg/kg body weight</li><li>Early Embryonic Development: NOAEL: 0.5 mg/kg body weight</li><li>Method: Study of Fertility and Early Embryonic Development to Implantation</li></ul><br><ul style="list-style-type: none"><li>Test Type: Fertility/early embryonic development</li><li>Species: Rat, females</li><li>Application Route: Subcutaneous</li><li>General Toxicity Parent: NOAEL: 5 mg/kg body weight</li><li>Method: Study of Fertility and Early Embryonic Development to Implantation</li></ul> |
| Effects on fetal development       | : <ul style="list-style-type: none"><li>Test Type: Embryo-fetal development</li><li>Species: Rat</li><li>Application Route: Subcutaneous</li><li>General Toxicity Maternal: NOAEL: 50 mg/kg body weight</li><li>Developmental Toxicity: NOAEL: 5 mg/kg body weight</li></ul><br><ul style="list-style-type: none"><li>Test Type: Fertility/early embryonic development</li><li>Species: Rabbit</li><li>Application Route: Subcutaneous</li><li>General Toxicity Maternal: NOAEL: 5 mg/kg body weight</li><li>Developmental Toxicity: NOAEL: 0.5 mg/kg body weight</li></ul>   |
| Reproductive toxicity - Assessment | : <ul style="list-style-type: none"><li>Clear evidence of adverse effects on development, based on animal experiments., Clear evidence of adverse effects on sexual function and fertility, based on animal experiments.</li></ul>  |

### STOT-single exposure

Not classified based on available information.

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### Components:

#### Sotatercept:

Remarks : No data available

### STOT-repeated exposure

Causes damage to organs (Blood, Immune system, Liver) through prolonged or repeated exposure.

### Components:

#### Sotatercept:

Target Organs : Blood, Immune system, Liver  
Assessment : Causes damage to organs through prolonged or repeated exposure.  
Remarks : Based on human experience.

### Repeated dose toxicity

### Components:

#### Sotatercept:

Species : Rat, male and female  
NOAEL : 3 mg/kg  
Application Route : Intravenous  
Exposure time : 3 Months  
Number of exposures : Once weekly  
Target Organs : Blood, male reproductive organs

Species : Monkey, male and female  
NOAEL : 30 mg/kg  
Application Route : Intravenous  
Exposure time : 3 Months  
Number of exposures : Once weekly  
Target Organs : Blood, Kidney

Species : Monkey, male and female  
NOAEL : 1 mg/kg  
Application Route : Intravenous  
Exposure time : 9 Months  
Number of exposures : Once every 4 weeks  
Target Organs : Blood, Kidney, Immune system

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

### Components:

#### Sotatercept:

General Information : Well tolerated in clinical use  
Inhalation : Remarks: No data available

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|              |                              |
|--------------|------------------------------|
| Skin contact | : Remarks: No data available |
| Eye contact  | : Remarks: No data available |
| Ingestion    | : Remarks: No data available |

### Further information

#### Components:

#### Sotatercept:

|         |                                  |
|---------|----------------------------------|
| Remarks | : Well tolerated in clinical use |
|---------|----------------------------------|

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

No data available

### Persistence and degradability

No data available

### Bioaccumulative potential

#### Components:

#### Sucrose:

|  |            |
|--|------------|
| Partition coefficient: n-octanol/water | : Pow: < 1 |
|--|------------|

### Mobility in soil

No data available

### Other adverse effects

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

|                        |   |
|------------------------|---|
| Waste from residues    | : Do not dispose of waste into sewer.<br>Dispose of in accordance with local regulations.   |
| Contaminated packaging | : Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product. |

## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

Not regulated as a dangerous good

#### IATA-DGR

Not regulated as a dangerous good

#### IMDG-Code

Not regulated as a dangerous good

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### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Domestic regulation

#### TDG

Not regulated as a dangerous good

### Special precautions for user

Not applicable

## SECTION 15. REGULATORY INFORMATION

### The ingredients of this product are reported in the following inventories:

|       |   |                |
|-------|---|----------------|
| AICS  | : | not determined |
| DSL   | : | not determined |
| IECSC | : | not determined |

## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

|                    |   |   |
|--------------------|---|---|
| ACGIH              | : | USA. ACGIH Threshold Limit Values (TLV)   |
| CA AB OEL          | : | Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)   |
| CA BC OEL          | : | Canada. British Columbia OEL  |
| CA QC OEL          | : | Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants |
| ACGIH / TWA        | : | 8-hour, time-weighted average   |
| CA AB OEL / TWA    | : | 8-hour Occupational exposure limit  |
| CA BC OEL / TWA    | : | 8-hour time weighted average  |
| CA QC OEL / TWA EV | : | Time-weighted average exposure value  |

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships;

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n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 06/17/2025  
Date format : mm/dd/yyyy

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

CA / Z8