SAFETY DATA SHEET

SUSVIMO 10MG/0.1ML VIAL TYP-RSTO EX-VE

SECTION 1. IDENTIFICATION

Product name: SUSVIMO 10MG/0.1ML VIAL TYP-RSTO EX-VE
Product code: 00010233092

Manufacturer or supplier’s details
Company name of supplier: Genentech, Inc.
Address: DNA Way 1
94080 South San Francisco
CA
USA
Telephone: 001-(650) 225-1000
E-mail address: info.sds@roche.com
Emergency telephone number: US Chemtrec phone (800)-424-9300

Recommended use of the chemical and restrictions on use
Recommended use: Formulated pharmaceutical active substance
Restrictions on use: For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranibizumab</td>
<td>347396-82-1</td>
<td>10.0</td>
</tr>
<tr>
<td>.alpha.-D-Glucopyranoside, .beta.-D-</td>
<td>57-50-1</td>
<td>8.22</td>
</tr>
<tr>
<td>fructofuranosyl</td>
<td></td>
<td></td>
</tr>
<tr>
<td>L-Histidine monohydrochloride</td>
<td>5934-29-2</td>
<td>0.17</td>
</tr>
<tr>
<td>monohydrate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>L-Histidine</td>
<td>71-00-1</td>
<td>0.03</td>
</tr>
<tr>
<td>Sorbitan, monododecanoate,</td>
<td>9005-64-5</td>
<td>0.01</td>
</tr>
</tbody>
</table>
SECTION 4. FIRST AID MEASURES

General advice : Do not leave the victim unattended.

If inhaled : Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.

In case of skin contact : If on skin, rinse well with water.

In case of eye contact : Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
If eye irritation persists, consult a specialist.

If swallowed : Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Rinse mouth with water.

Most important symptoms and effects, both acute and delayed : None known.

Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards during fire fighting : No information available.

Hazardous combustion products : In case of fire hazardous decomposition products may be produced such as: Carbon monoxide Nitrogen oxides (NOx)

Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.
SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Refer to protective measures listed in sections 7 and 8.

Environmental precautions: Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Wipe up with absorbent material (e.g. cloth, fleece). Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion: Normal measures for preventive fire protection.

Advice on safe handling: For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area.

Conditions for safe storage: Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions: See label, package insert or internal guidelines

Materials to avoid: No materials to be especially mentioned.

Storage temperature: Protected from heat and light
Do not shake solution

Further information on storage stability: No decomposition if stored and applied as directed.

Packaging material: Suitable material: Stainless steel, glass, Vials

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Ingredients with workplace control parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
</tr>
<tr>
<td>Ranibizumab</td>
</tr>
<tr>
<td>.alpha.-D</td>
</tr>
</tbody>
</table>
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Glucopyranoside, β-D-fructofuranosyl

<table>
<thead>
<tr>
<th></th>
<th>TWA (Respirable)</th>
<th>TWA (total)</th>
<th>TWA (total dust)</th>
<th>TWA (respirable fraction)</th>
<th>TWA (Total dust)</th>
<th>TWA (respirable dust fraction)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5 mg/m³</td>
<td>10 mg/m³</td>
<td>15 mg/m³</td>
<td>5 mg/m³</td>
<td>15 mg/m³</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>NIOSH REL</td>
<td>NIOSH REL</td>
<td>OSHA Z-1</td>
<td>OSHA Z-1</td>
<td>OSHA P0</td>
<td>OSHA P0</td>
</tr>
</tbody>
</table>

Engineering measures : No data available

Personal protective equipment
Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection
Material : Protective gloves
Remarks : Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.

Eye protection : Safety glasses

Skin and body protection : Protective suit

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution, Sterile liquid
Color : clear, colorless
Odor : No data available
Odor Threshold : No data available
pH : 5.5
Melting point/range : No data available
Boiling point/boiling range : No data available
Flash point : does not flash
Evaporation rate : No data available
Flammability (solid, gas) : Does not sustain combustion.
Flammability (liquids) : Does not sustain combustion.
Self-ignition : Not applicable
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapor pressure : No data available
Relative vapor density : No data available
Relative density : No data available
Solubility(ies)
  Water solubility : completely miscible
  Solubility in other solvents : No data available
Partition coefficient: n-octanol/water : Remarks: No data available
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity
  Viscosity, dynamic : No data available
  Viscosity, kinematic : No data available
Explosive properties : No data available
Oxidizing properties : No data available

SECTION 10. STABILITY AND REACTIVITY
Reactivity : No dangerous reaction known under conditions of normal use.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Stable under recommended storage conditions. No hazards to be specially mentioned.
Conditions to avoid : No data available
Incompatible materials : No data available
Hazardous decomposition : No data available
SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Not classified based on available information.

Components:

Ranibizumab:
Acute oral toxicity : Remarks: Not bioavailable by oral administration

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:
Acute oral toxicity : LD50 Oral (Rat): 29,700 mg/kg
LD50 Oral (Mouse): 14,000 mg/kg
Acute inhalation toxicity :
Acute toxicity estimate: > 30 mg/l
Test atmosphere: dust/mist
Method: Expert judgment
Acute dermal toxicity :
Acute toxicity estimate: > 5,001 mg/kg
Method: Expert judgment

Skin corrosion/irritation
Not classified based on available information.

Serious eye damage/eye irritation
Not classified based on available information.

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Carcinogenicity
Not classified based on available information.

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:
Remarks : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

IARC : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA : No component of this product present at levels greater than or equal to 0.1% is
on OSHA’s list of regulated carcinogens.

**NTP**
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**Reproductive toxicity**
Not classified based on available information.

**Components:**

**Ranibizumab:**
Effects on fetal development: Result: Based on its mechanism of action, effects on embryofetal development can be assumed.

**STOT-single exposure**
Not classified based on available information.

**Components:**

**.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**
Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

**STOT-repeated exposure**
Not classified based on available information.

**Components:**

**.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**
Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

**Aspiration toxicity**
Not classified based on available information.

**Components:**

**.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**
No data available

**Further information**

**Components:**

**Ranibizumab:**
Remarks: anaphylactic reactions may occur following the intravenous application of proteins; rare cases of hypersensitivity have been described with other monoclonal antibodies

**.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**
Remarks: Health injuries are not known or expected under normal use.
SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:
Toxicity to fish : LC50: > 100 mg/l
Exposure time: 96 h

Ecotoxicology Assessment
Acute aquatic toxicity : This product has no known ecotoxicological effects.
Chronic aquatic toxicity : This product has no known ecotoxicological effects.
Toxicity Data on Soil : Not expected to adsorb on soil.
Other organisms relevant to the environment : No data available

Persistence and degradability

Components:

Ranibizumab:
Biodegradability : Result: Globular proteins are generally well biodegradable

Bioaccumulative potential

Components:

Ranibizumab:
Partition coefficient: n-octanol/water : Remarks: No data available

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:
Partition coefficient: n-octanol/water : log Pow: -3.67

Mobility in soil
No data available

Other adverse effects

Product:
Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
Components:

Ranibizumab:
Additional ecological information: Monoclonal antibodies are proteins with highly specific affinity to a certain antigen; therefore, no appreciable ecotoxic potential is to be expected

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Can be disposed as waste water, when in compliance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers.

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
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation
49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know
CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.
SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.
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SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component TPQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARA 311/312 Hazards</td>
<td>No SARA Hazards</td>
<td></td>
</tr>
</tbody>
</table>

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. Clean Water Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. Clean Water Act, Section 311, Table 117.3.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know

'.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl' 57-50-1

Pennsylvania Right To Know

Water 7732-18-5
Ranibizumab 347396-82-1
'.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl' 57-50-1

Maine Chemicals of High Concern

Vermont Chemicals of High Concern

Washington Chemicals of High Concern

California Permissible Exposure Limits for Chemical Contaminants

'.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl' 57-50-1

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

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DSL</td>
<td>This product contains the following components that are not on the Canadian DSL nor NDSL.</td>
</tr>
<tr>
<td></td>
<td>Ranibizumab</td>
</tr>
<tr>
<td></td>
<td>L-Histidine monohydrochloride monohydrate</td>
</tr>
<tr>
<td>AICS</td>
<td>Not in compliance with the inventory</td>
</tr>
<tr>
<td>NZIoC</td>
<td>On the inventory, or in compliance with the inventory</td>
</tr>
<tr>
<td>ENCS</td>
<td>Not in compliance with the inventory</td>
</tr>
<tr>
<td>ISHL</td>
<td>Not in compliance with the inventory</td>
</tr>
</tbody>
</table>
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KECI : Not in compliance with the inventory
PICCS : Not in compliance with the inventory
IECSC : Not in compliance with the inventory
TCSI : Not in compliance with the inventory
TSCA : Substance(s) not listed on TSCA inventory

TSCA list
No substances are subject to a Significant New Use Rule.
No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

Further information

NFPA:  
HMIS® IV:

Flammability  
Health  
Instability  
Special hazard.

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH  : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA P0  : USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA  : 8-hour, time-weighted average
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA : 8-hour time weighted average
OSHA Z-1 / TWA : 8-hour time weighted average
Revision Date : 07-30-2019

The information provided in this Material 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.

US / Z8 / 1805