

LUNSUMIO Vials 1 mg/1 ml

Version 1.1 Revision Date: 02-06-2023 Date of last issue: 01-04-2021
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SECTION 1. IDENTIFICATION

Product name : LUNSUMIO Vials 1 mg/1 ml
Product code : 00010200133
Common name(s), syno- : anti-CD20/CD3 TDB
nym(s) of the substance Bispecific human anti-CD20/CD3 TDB antibody

Manufacturer or supplier's details

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

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 the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Hazardous properties cannot be ruled out. Always exercise caution and follow good industrial hygiene practices when handling chemicals.

Not a hazardous substance or mixture.

GHS label elements

Hazardous properties cannot be ruled out. Always exercise caution and follow good industrial hygiene practices when handling chemicals.

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|---------------|---------|-----------------------|
|---------------|---------|-----------------------|

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| | | |
|-------------------------------------------------------------|--------------|-------|
| Mosunetuzumab | 1905409-39-3 | 0.1 |
| .alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl | 57-50-1 | 8.2 |
| L-Histidine | 71-00-1 | 0.16 |
| L-Methionine | 63-68-3 | 0.15 |
| Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs. | 9005-64-5 | < 0.1 |
| Acetic acid | 64-19-7 | < 0.1 |
| Water | 7732-18-5 | > 91 |

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 : No hazardous combustion products are known
- Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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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 : Avoid exposure
 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 : Store between +2°C and +8C.
 Do not freeze.
 Store protected from light
 Do not shake solution

Electrical installations / working materials must comply with the technological safety standards.

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.

Further information on storage stability : No decomposition if stored and applied as directed.
 Do not freeze.

No decomposition if stored and applied as directed.

Packaging material : Suitable material: Ampoules, Prefilled syringes, Vials

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

| Components | CAS-No. | Value type | Control parame- | Basis |
|------------|---------|------------|-----------------|-------|
|------------|---------|------------|-----------------|-------|

SAFETY DATA SHEET

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| | | (Form of exposure) | ters / Permissible concentration | |
|-----------------------------------------------------|--------------|--------------------------------|----------------------------------|-------------------------------------------|
| .alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl | 57-50-1 | TWA | 10 mg/m ³ | ACGIH |
| | | TWA (Respirable) | 5 mg/m ³ | NIOSH REL |
| | | TWA (total) | 10 mg/m ³ | NIOSH REL |
| | | TWA (total dust) | 15 mg/m ³ | OSHA Z-1 |
| | | TWA (respirable fraction) | 5 mg/m ³ | OSHA Z-1 |
| | | TWA (Total dust) | 15 mg/m ³ | OSHA P0 |
| | | TWA (respirable dust fraction) | 5 mg/m ³ | OSHA P0 |
| Mosunetuzumab | 1905409-39-3 | IOEL | 0.004 mg/m ³ | Roche Industrial Hygiene Committee (RIHC) |

Engineering measures : No data available

Personal protective equipment

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.

No personal respiratory protective equipment normally required.

Hand protection

In case of contact through splashing:
Material : Nitrile rubber
Break through time : > 30 min
Glove thickness : > 0.11 mm

In case of full contact:
Material : butyl-rubber
Break through time : > 480 min
Glove thickness : > 0.4 mm

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

Protective measures : Instruction of employees recommended

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

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| | | |
|--------------------------------------------------|---|-------------------|
| Appearance | : | Clear liquid |
| Color | : | colorless |
| Odor | : | No data available |
| Odor Threshold | : | No data available |
| pH | : | 5.8 |
| Melting point/range | : | No data available |
| Boiling point/boiling range | : | No data available |
| Flash point | : | does not flash |
| Evaporation rate | : | No data available |
| 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 | : | No data available |
| Solubility in other solvents | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| Autoignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity | | |
| Viscosity, dynamic | : | No data available |
| Viscosity, kinematic | : | No data available |

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Explosive 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.

Does not contain any antimicrobial preservative; therefore, care must be taken to ensure the sterility of the prepared solution

Proteins are temperature-sensitive; the thermal denaturation has an impact on quality but does not affect Plant and Process Safety; during decomposition no flammable gas, no organic peroxide and no oxidising substances are created

Possibility of hazardous reactions : No data available
Stable under recommended storage conditions.
No hazards to be specially mentioned.

Conditions to avoid : No data available

Incompatible materials : No data available

Hazardous decomposition products : No decomposition if stored and applied as directed.

SECTION 11. TOXICOLOGICAL INFORMATION
Acute toxicity

Not classified based on available information.

Components:
Mosunetuzumab:

Acute oral toxicity : Remarks: Not bioavailable by oral administration

Acute toxicity (other routes of administration) : HNSTD (Highest Non-Severely Toxic Dose) (cynomolgus monkey): > 1 mg/kg
Application Route: i.v.
GLP: yes

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

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

L-Histidine:

Acute oral toxicity : LD50 Oral (Rat): > 15,000 mg/kg

LD50 Oral (Mouse): > 15,000 mg/kg

L-Methionine:

Acute oral toxicity : Acute toxicity estimate (Rat): > 5,000 mg/kg

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Method: Expert judgment

Acute toxicity estimate (Mouse): > 5,000 mg/kg
Method: Expert judgment

Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l
Test atmosphere: dust/mist
Method: Expert judgment

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Expert judgment

Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.:

Acute oral toxicity : LD50 Oral (Rat): 38,900 mg/kg

Acetic acid:

Acute oral toxicity : LD50 Oral (Rat, male and female): 3,310 mg/kg
GLP: no

Acute inhalation toxicity : LC50 (Rat, male and female): 11.4 mg/l
Exposure time: 4 h
Test atmosphere: vapor
GLP: no
Assessment: The substance or mixture has no acute inhalation toxicity

Skin corrosion/irritation

Not classified based on available information.

Components:**L-Methionine:**

Remarks : This information is not available.

Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.:

Species : Rabbit
Result : No skin irritation

Acetic acid:

Species : Rabbit
Exposure time : 4 h
Method : OECD Test Guideline 404
Result : Causes severe burns.
GLP : No information available.

Serious eye damage/eye irritation

Not classified based on available information.

Components:**L-Methionine:**

Remarks : This information is not available.

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Result : No eye irritation**Acetic acid:**Species : Rabbit
Result : Risk of serious damage to eyes.
Exposure time : 4 h
Method : OECD Test Guideline 405
GLP : No information available.**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.:**Species : Guinea pig
Result : Not a skin sensitizer.**Germ cell mutagenicity**

Not classified based on available information.

Components:**.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative**Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.:**Genotoxicity in vitro : Test Type: Micronucleus test
Test system: Escherichia coli
Result: negative

Germ cell mutagenicity - Assessment : Tests on bacterial or mammalian cell cultures did not show mutagenic effects.

Acetic acid:Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: Metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: No information available.
Remarks: In vitro tests did not show mutagenic effects

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Test Type: Chromosome aberration test in vitro
 Test system: Chinese hamster ovary cells
 Metabolic activation: with and without metabolic activation
 Method: OECD Test Guideline 473
 Result: negative
 GLP: no
 Remarks: In vitro tests did not show mutagenic effects

Genotoxicity in vivo : Test Type: Micronucleus test
 Species: Rat (male and female)
 Application Route: Inhalation
 Exposure time: 13 weeks
 Dose: 0, 1, 5, 20 ppm
 Method: Mutagenicity (micronucleus test)
 Result: negative
 GLP: yes

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.

L-Histidine:

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.

Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.:

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.

Acetic acid:

Species : Mouse, female
 Application Route : Dermal
 Exposure time : 32 weeks
 Result : negative
 GLP : no
 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.

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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:**Mosunetuzumab:**

Effects on fertility : Species: cynomolgus monkey
Result: No adverse effects.

Acetic acid:

Effects on fetal development : Species: Mouse, female
Application Route: Oral
Dose: 10 ml/kg body weight
Duration of Single Treatment: 6 - 15 d
Developmental Toxicity: NOAEL: 345 mg/kg body weight
Method: Regulation (EC) No. 440/2008, Annex, B.31
GLP: No information available.

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.

L-Methionine:

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.

L-Methionine:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration toxicity

Not classified based on available information.

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No data available

L-Methionine:

No data available

Further information**Components:****Mosunetuzumab:**

Remarks : Globular proteins are generally well biodegradable

.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:****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**L-Methionine:**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**Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.:**

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- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 216 mg/l
 Exposure time: 96 h
- LC50 (Brachydanio rerio (zebrafish)): > 100 mg/l
 Exposure time: 96 h
 Method: OECD Test Guideline 203
 GLP: yes
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
 Exposure time: 48 h
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOELR (Daphnia): 10 mg/l
 Exposure time: 21 d
 Method: OECD Test Guideline 211
- Toxicity to microorganisms : EC0 (Pseudomonas putida): > 10,000 mg/l
- EC50 (Bacteria): 774 mg/l
 Exposure time: 5 h

Acetic acid:

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 300.82 mg/l
 End point: mortality
 Exposure time: 96 h
 Test Type: semi-static test
 Analytical monitoring: no
 Method: OECD Test Guideline 203
 GLP: yes
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 300.82 mg/l
 End point: Immobilization
 Exposure time: 48 h
 Test Type: static test
 Analytical monitoring: yes
 Method: OECD Test Guideline 202
 GLP: yes
- Toxicity to algae/aquatic plants : EC50 (Skeletonema costatum (marine diatom)): > 300.82 mg/l
 Exposure time: 72 h
 Test Type: static test
 Analytical monitoring: no
 GLP: yes

Persistence and degradability**Components:****Mosunetuzumab:**

- Biodegradability : Result: Globular proteins are generally well biodegradable

Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.:

- Biodegradability : Result: Readily biodegradable.
 Biodegradation: > 70 %
 Exposure time: 28 d

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Method: OECD Test Guideline 301B

Acetic acid:

Biodegradability : aerobic
 Inoculum: activated sludge
 Concentration: 3 mg/l
 Result: Readily biodegradable.
 Biodegradation: 96 %
 Exposure time: 20 d
 GLP: no

Bioaccumulative potential**Components:****Mosunetuzumab:**

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

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Partition coefficient: n-
 octanol/water : log Pow: -3.7 (68 °F / 20 °C)

L-Histidine:

Partition coefficient: n-
 octanol/water : Remarks: Not applicable

L-Methionine:

Partition coefficient: n-
 octanol/water : log Pow: -1.87

Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.:

Bioaccumulation : Remarks: No data available

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

Acetic acid:

Bioaccumulation : Bioconcentration factor (BCF): 3.16

Partition coefficient: n-
 octanol/water : log Pow: -0.17 (77 °F / 25 °C)
 pH: 7
 Method: No information available.
 GLP: No information available.

Water:

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

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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:

Mosunetuzumab:

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

L-Histidine:

Additional ecological information : No data available

L-Methionine:

Adsorbed organic bound halogens (AOX) : Remarks: Not applicable

Additional ecological information : No data available

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

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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

Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

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 SOCM I Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

| | | |
|-------------|---------|----------------|
| Acetic acid | 64-19-7 | >= 0 - < 0.1 % |
|-------------|---------|----------------|

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

| | | |
|-------------|---------|----------------|
| Acetic acid | 64-19-7 | >= 0 - < 0.1 % |
|-------------|---------|----------------|

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

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US State Regulations

Massachusetts Right To Know

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

Pennsylvania Right To Know

| | |
|-----------------------------------------------------|-----------|
| Water | 7732-18-5 |
| .alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl | 57-50-1 |
| Acetic acid | 64-19-7 |

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

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:

- AIIC : Not in compliance with the inventory
- DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Mosunetuzumab
- NZIoC : On the inventory, or in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- 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 : Product contains substance(s) not listed on TSCA inventory.
- TECI : Not in compliance with the 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

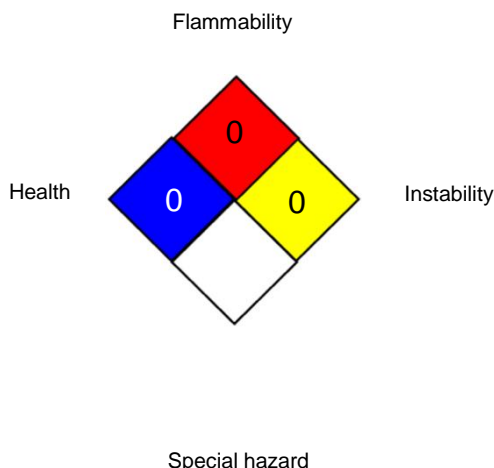
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NFPA 704:



HMIS® IV:

| | | |
|------------------------|---|---|
| HEALTH | / | 0 |
| FLAMMABILITY | | 0 |
| PHYSICAL HAZARD | | 0 |

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. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
- 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

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office

LUNSUMIO Vials 1 mg/1 ml

Version
1.1

Revision Date:
02-06-2023

Date of last issue: 01-04-2021
Date of first issue: 01-04-2021

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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECl - 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

Revision Date : 02-06-2023

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.

US / Z8 / 2204