

**LUNSUMIO Vials 30 mg/30 ml**

Version 1.1                      Revision Date: 02-06-2023                      Date of last issue: 01-04-2021  
Date of first issue: 01-04-2021

**SECTION 1. IDENTIFICATION**

Product name                      : LUNSUMIO Vials 30 mg/30 ml  
Product code                      : 00010221576  
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.

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**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.

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**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture                      : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
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# SAFETY DATA SHEET

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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
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		(Form of exposure)	ters / Permissible concentration	
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Total dust)	15 mg/m <sup>3</sup>	OSHA P0
		TWA (respirable dust fraction)	5 mg/m <sup>3</sup>	OSHA P0
Mosunetuzumab	1905409-39-3	IOEL	0.004 mg/m <sup>3</sup>	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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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

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.

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**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

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## 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.

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## 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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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 &gt;= 0 - &lt; 0.1 %

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

Acetic acid 64-19-7 &gt;= 0 - &lt; 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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.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**



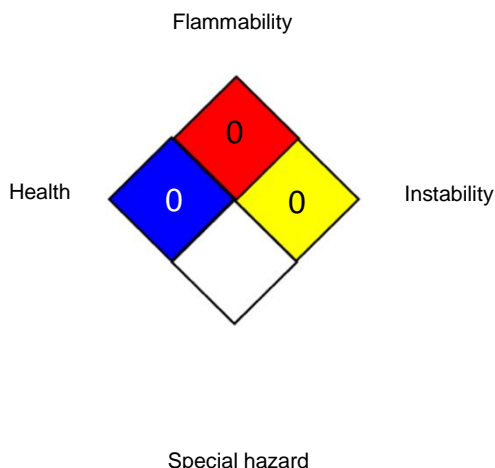
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**NFPA 704:**



**HMIS® IV:**

<b>HEALTH</b>	/	0
<b>FLAMMABILITY</b>		0
<b>PHYSICAL HAZARD</b>		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 30 mg/30 ml

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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

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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.

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