

**COLUMVI 10MG/10ML 1VL TY-PZ EX-SSF**

Version 2.0                      Revision Date: 04-27-2023                      Date of last issue: 03-16-2023  
 Date of first issue: 03-16-2023

**SECTION 1. IDENTIFICATION**

Product name                      : COLUMVI 10MG/10ML 1VL TY-PZ EX-SSF  
 Product code                      : 00010229979  
 Common name(s), syno-            : Glofitamab (RO7082859) 0.1% aqueous solution  
 nym(s) of the substance            CD20 CD3 TCB (RO7082859) 0.1% aqueous solution

**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)**

Not a hazardous substance or mixture.

**GHS label elements**

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

**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)
Glofitamab	2229047-91-8	0.1
L-Histidine monohydrochloride monohydrate	5934-29-2	0.3
L-Histidine	71-00-1	< 0.1
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1	8.2

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L-Methionine	63-68-3	0.15
Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.	9005-64-5	0.05
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.
- Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

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

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1	TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
Glofitamab	2229047-91-	IOEL	0.0001 mg/m3	Roche In-

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	8			Industrial Hygiene Committee (RIHC)
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**Engineering measures** : No data available

**Personal protective equipment**

Respiratory protection : 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

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 : Clear liquid, Sterile liquid

Color : colorless, clear

pH : 5.5

Flash point : does not flash

Flammability (solid, gas) : Does not sustain combustion.

Flammability (liquids) : Does not sustain combustion.

Solubility(ies)  
Water solubility : completely miscible

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

**SECTION 10. STABILITY AND REACTIVITY**

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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.

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**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Not classified based on available information.

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

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

**Glofitamab:**

Acute oral toxicity : Remarks: Not bioavailable by oral administration

Acute toxicity (other routes of administration) : NOAEL (No observed adverse effect level) (cynomolgus monkey): 0.1 mg/kg  
Application Route: parenteral  
GLP: no

**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.

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

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

**Carcinogenicity**

Not classified based on available information.

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

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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.

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

Remarks : Health injuries are not known or expected under normal use.

**Glofitamab:**

Remarks : anaphylactic reactions may occur following the intravenous application of proteins; after inhalative exposure no cases of hypersensitivity have been described

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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**Persistence and degradability****Components:****Glofitamab:**

Biodegradability : Result: Globular proteins are generally well biodegradable

**Bioaccumulative potential****Components:****.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**Partition coefficient: n-  
octanol/water : log Pow: -3.7 (68 °F / 20 °C)**Glofitamab:**Partition coefficient: n-  
octanol/water : Remarks: No data available**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).

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### **Components:**

#### **Glofitamab:**

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

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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

##### **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**

Not applicable

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### SECTION 15. REGULATORY INFORMATION

#### **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.

#### **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



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**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 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. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

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

**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

**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.

L-Histidine monohydrochloride monohydrate

Glofitamab

NZIoC : On the inventory, or in compliance with the inventory

ENCS : Not in compliance with the inventory

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- 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

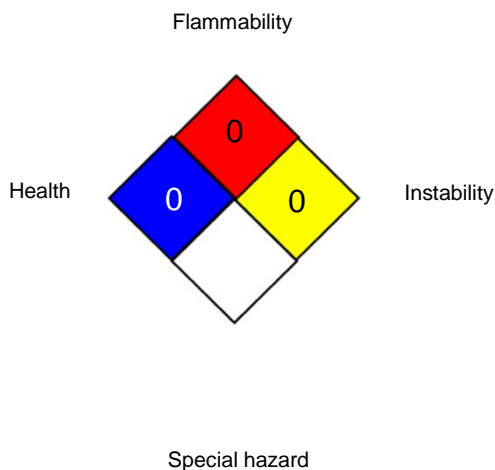
**TSCA list**

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**

**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

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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 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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