

RITUXAN HYCELA Vials 1600 mg/13.4 mlVersion
1.0Revision Date:
06/14/2025Date of last issue: -
Date of first issue: 06/14/2025**SECTION 1. IDENTIFICATION**

Product name : RITUXAN HYCELA Vials 1600 mg/13.4 ml

Product code : RO045-2294/F05-01

Common name(s),
synonym(s) of the substance : RITUXAN HYCELA(TM) Vials**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

In case of emergencies: : US CHEMTREC PHONE (800)-424-9300

Recommended use of the chemical and restrictions on use

Recommended use : Formulated pharmaceutical active substance

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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Rituximab	174722-31-7	12
Hyaluronidase	757971-58-7	0.003
Trehalose (D+)-, 2H ₂ O	6138-23-4	7.92
L-Histidine monohydrochloride monohydrate	5934-29-2	0.35
L-Histidine	71-00-1	0.05
L-Methionine	63-68-3	0.15
Sorbitan, mono-(9Z)-9-	9005-65-6	0.06

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octadecenoate, poly(oxy-1,2-ethanediyl) derivs.		
Water	7732-18-5	79

SECTION 4. FIRST AID MEASURES

General advice	: Do not leave the victim unattended.
If inhaled	: If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.
In case of skin contact	: Wash off with soap and water.
In case of eye contact	: 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.
Most important symptoms and effects, both acute and delayed	: None known.
Protection of first-aiders	: First Aid responders should pay attention to self-protection and use the recommended protective clothing
Notes to physician	: Treat symptomatically.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	: High volume water jet
Specific hazards during fire fighting	: No information available.
Hazardous combustion products	: Carbon monoxide Nitrogen oxides (NOx) Carbon oxides
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 : Wear self-contained breathing apparatus for firefighting if
for fire-fighters necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

Environmental precautions : If the product contaminates rivers and lakes or drains inform
respective authorities.

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

SECTION 7. HANDLING AND STORAGE

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

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.

Materials to avoid : No materials to be especially mentioned.

Storage temperature : Protect from heat and light

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

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Rituximab	174722-31-7	IOEL	0.04 mg/m ³	Roche Industrial Hygiene Committee (RIHC)

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Hyaluronidase	757971-58-7	IOEL	0.00006 mg/m3	Roche Industrial Hygiene Committee (RIHC)
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Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

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

Hygiene measures : General industrial hygiene practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Clear liquid, Sterile liquid

Color : colorless, light yellow

Odor : No data available

Odor Threshold : No data available

pH : 5.0 - 6.0

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Melting point/ range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Self-ignition	:	No data available
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
Density	:	No data available
Solubility(ies)		
Water solubility	:	completely miscible
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
Explosive properties	:	No data available
Oxidizing properties	:	No data available
Particle characteristics		
Particle Size Distribution	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
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Chemical stability	:	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 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 Not applicable
Hazardous decomposition products	:	No data available No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified due to lack of data.

Components:**Rituximab:**

Acute oral toxicity : Remarks: Not bioavailable by oral administration

Acute toxicity (other routes of administration) : Maximum tolerated dose (Mouse): > 100 mg/kg
Application Route: i.p.**Trehalose (D+)-, 2H₂O:**Acute oral toxicity : LD₅₀ (Rat): 16,000 mg/kg**Hyaluronidase:**

Acute oral toxicity : Remarks: Not bioavailable by oral administration

Skin corrosion/irritation

Not classified due to lack of data.

Components:**Hyaluronidase:**

Remarks : This information is not available.

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Not classified due to lack of data.

Components:**Hyaluronidase:**

Remarks : This information is not available.

Respiratory or skin sensitization**Skin sensitization**

Not classified due to lack of data.

Respiratory sensitization

Not classified due to lack of data.

Components:**Hyaluronidase:**

Remarks : May cause sensitization of susceptible persons by skin contact or by inhalation of dust.

Germ cell mutagenicity

Not classified due to lack of data.

Carcinogenicity

Not classified due to lack of data.

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 due to lack of data.

STOT-single exposure

Not classified due to lack of data.

Components:**Hyaluronidase:**

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

STOT-repeated exposure

Not classified due to lack of data.

Components:**Hyaluronidase:**

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

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Species : cynomolgus monkey
NOAEL : 2 mg/kg/w
Application Route : s.c.
Exposure time : 39 weeks

Aspiration toxicity

Not classified due to lack of data.

Components:**Hyaluronidase:**

No data available

Further information**Product:**

Remarks : No data available

Components:**Rituximab:**

Remarks : after parenteral application, rare cases of hypersensitivity, including anaphylactic shock, can occur

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Trehalose (D+)-, 2H₂O:**

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l
Exposure time: 96 h
Test Type: static test

Toxicity to fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): 100 mg/l
Exposure time: 96 d

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

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Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Persistence and degradability**Components:****Rituximab:**

Biodegradability : Result: Globular proteins are generally well biodegradable

Trehalose (D+)-, 2H₂O:

Biodegradability : aerobic
Inoculum: activated sludge, non-adapted
Biochemical oxygen demand
Result: Readily biodegradable.
Biodegradation: 73 %
Method: OECD Test Guideline 301A
Remarks: The 10 day time window criterion is not fulfilled.

aerobic
Inoculum: activated sludge, non-adapted
Dissolved organic carbon (DOC)
Result: Readily biodegradable.
Biodegradation: 98 %
Method: OECD Test Guideline 301A

Hyaluronidase:

Biodegradability : Result: Globular proteins are generally well biodegradable

Bioaccumulative potential**Components:****Rituximab:**

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

Trehalose (D+)-, 2H₂O:

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

Hyaluronidase:

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

Mobility in soil

No data available

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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).

Additional ecological
information : No data available

Components:**Rituximab:**

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

Hyaluronidase:

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.

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

Domestic regulation

49 CFR

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Not regulated as a dangerous good

Special precautions for userRemarks : Not dangerous goods in the meaning of ADR/RID, ADN,
IMDG-Code, ICAO/IATA-DGR**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

Components	CAS-No.	Component TPQ (lbs)
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SARA 311/312 Hazards : No SARA Hazards**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****Pennsylvania Right To Know**

Water	7732-18-5
Rituximab	174722-31-7
Trehalose (D+)-, 2H2O	6138-23-4

Maine Chemicals of High Concern**Vermont Chemicals of High Concern****Washington Chemicals of High Concern****The ingredients of this product are reported in the following inventories:**

AllC : Not in compliance with the inventory

DSL : This product contains the following components that are not
on the Canadian DSL nor NDSL.

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Rituximab

L-Histidine monohydrochloride monohydrate

Hyaluronidase

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.

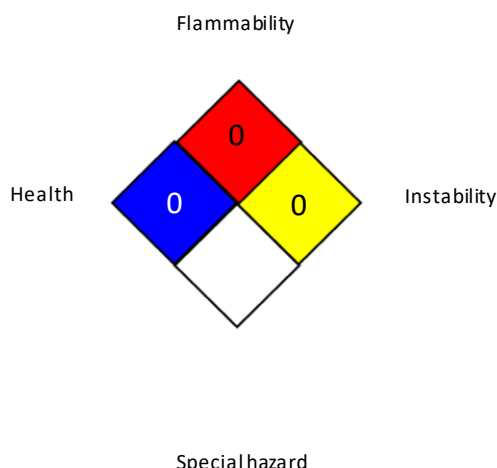
SECTION 16. OTHER INFORMATION**Further information**

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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

AIIIC - 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; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United

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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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