

HERCEPTIN(R) Vials (440 mg)

Version 1.1 Revision Date: 02-10-2020 Date of last issue: 04-18-2019
 Date of first issue: 04-18-2019

SECTION 1. IDENTIFICATION

Product name : HERCEPTIN(R) Vials (440 mg)
 Product code : 00010086840
 Common name(s), syno- : HERCEPTIN lyophilized Vials
 nym(s) of the substance recombinant humanised monoclonal antibody (Trastuzumab)
 with excipients

Manufacturer or supplier's details

Company name of supplier : Genentech, Inc.
 Address : DNA Way 1
 94080 South San Francisco
 CA
 USA
 Telephone : 001-(650) 225-1000
 E-mail address : info.sds@roche.com
 Emergency telephone
 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 29 CFR 1910.1200

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Trastuzumab	180288-69-1	51.31
Trehalose (D+)-, 2H ₂ O	6138-23-4	46.6
L-Histidine monohydrochloride mo- nohydrate	5934-29-2	1.15
L-Histidine	71-00-1	0.74
Sorbitan, monododecanoate,	9005-64-5	0.2

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poly(oxy-1,2-ethanediyl) derivs.		
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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

- Personal precautions, protective equipment and emergency measures : Avoid dust formation.

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gency procedures

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

Methods and materials for containment and cleaning up : Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Provide appropriate exhaust ventilation at places where dust is formed.

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. Store protected from light

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.

Packaging material : Suitable material: glass

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Trastuzumab	180288-69-1	IOEL	0.1 mg/m3	Roche Industrial Hygiene Committee (RIHC)

Engineering measures : No data available

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

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Material : Protective gloves

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

Eye protection : Safety glasses

Skin and body protection : Protective suit

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : solid, (lyophilized)

Color : off-white

Odor : Not applicable

Odor Threshold : Not applicable

pH : Not applicable

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 : 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 : Not applicable

Relative density : No data available

Solubility(ies)
Water solubility : completely soluble

Solubility in other solvents : No data available

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

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Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

 Viscosity, dynamic : Not applicable

 Viscosity, kinematic : Not applicable

Oxidizing properties : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.
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
Does not contain any antimicrobial preservative; therefore, care must be taken to ensure the sterility of the prepared solution

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

Conditions to avoid : Heat.

Incompatible materials : No data available

Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified based on available information.

Components:

Trastuzumab:

Acute oral toxicity : Remarks: Not bioavailable by oral administration

Acute toxicity (other routes of administration) : Maximum tolerated dose (Mouse): > 94 mg/kg
Application Route: i.v.

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

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Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

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

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

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

Reproductive toxicity

Not classified based on available information.

Components:

Trastuzumab:

Effects on fetal development : Result: Parenteral administration to pregnant women can cause fetal harm

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

Further information

Components:

Trastuzumab:

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

No data available

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Persistence and degradability

Components:

Trastuzumab:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 65 %
Exposure time: 14 d
Method: OECD Test Guideline 301F
GLP: yes

Result: Globular proteins are generally well biodegradable

Bioaccumulative potential

Components:

Trastuzumab:

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).

Components:

Trastuzumab:

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

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.

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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

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

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

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

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US State Regulations

Massachusetts Right To Know

Pennsylvania Right To Know

Trastuzumab	180288-69-1
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:

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

Trastuzumab

L-Histidine monohydrochloride monohydrate

AICS : Not in compliance with the inventory

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 : Substance(s) not listed on TSCA inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

SAFETY DATA SHEET

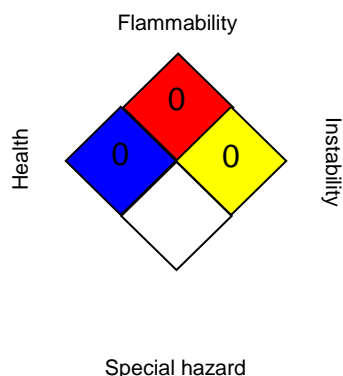
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NFPA:



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

AICS - Australian Inventory of Chemical Substances; 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; 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 Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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