# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard

Genentech
A Member of the Roche Group

## HERCEPTIN HYLECTA Vials 600 mg/5 ml

| Version | Revision Date: | Date of last issue: 06/14/2025 |
|---|---|---|
| 1.1 | 09/02/2026 | Date of first issue: 06/14/2025 |

### SECTION 1. IDENTIFICATION

| | | |
|---|---|---|
| Product name | : | HERCEPTIN HYLECTA Vials 600 mg/5 ml |
| Product code | : | RO045-2317/F07-02 |
| Common name(s), synonym(s) of the substance | : | HERCEPTIN Vials 600 mg/5 ml<br>HERCEPTIN SC ( (with Hyaluronidase) |

**Manufacturer or supplier's details**

| | | |
|---|---|---|
| Company name of supplier | : | Genentech, Inc. |
| Address | : | 1 DNA Way<br>South San Francisco, CA 94080<br>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)**

**Hazards for the product as supplied**

Not a hazardous substance or mixture.

**Other hazards**

None known.

**GHS label elements**

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

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name | CAS No./Unique ID | Concentration (% w/w) | Trade secret |
|---|---|---|---|
| Trastuzumab | 180288-69-1* | 12 | - |
| Hyaluronidase | 757971-58-7* | 0.0035 | - |
| Trehalose (D+)-), 2H2O | 6138-23-4* | 7.95 | - |
| L-Histidine monohydrochloride monohydrate | 5934-29-2* | 0.37 | - |
| L-Methionine | 63-68-3* | 0.15 | - |
| L-Histidine | 71-00-1* | 0.04 | - |
| Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs. | 9005-64-5* | 0.04 | - |
| Water | 7732-18-5* | 79 | - |

* Indicates that the identifier is a CAS No.

## 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.<br>Protect unharmed eye.<br>If eye irritation persists, consult a specialist. |
| If swallowed | : | Keep respiratory tract clear.<br>Do not give milk or alcoholic beverages.<br>Never give anything by mouth to an unconscious person.<br>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<br>Nitrogen oxides (NOx)<br>Carbon oxides |
| Further information | : | Standard procedure for chemical fires.<br>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 procedures | : | Avoid exposure<br>Refer to protective measures listed in sections 7 and 8. |
| Environmental precautions | : | If the product contaminates rivers and lakes or drains inform respective authorities. |
| Methods and materials for containment and cleaning up | : | Wipe up with absorbent material (e.g. cloth, fleece).<br>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.<br>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 storage stability | : | No decomposition if stored and applied as directed. |
| Packaging material | : | Suitable material: Stainless steel, 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) |
| Hyaluronidase | 757971-58-7 | IOEL | 0.00006 mg/m3 | Roche Industrial Hygiene Committee (RIHC) |

**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 |
| Protective measures | : | Instruction of employees recommended |
| Hygiene measures | : | General industrial hygiene practice. |

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|---|---|---|
| Appearance | : | Sterile liquid |
| Color | : | colorless, light yellow |

| | | |
|---|---|---|
| Odor | : | No data available |
| Odor Threshold | : | No data available |
| pH | : | 5.5 |
| 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 | : | 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 |
| 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. |
| Chemical stability | : | Stable under normal conditions. |

| | | |
|---|---|---|
| Possibility of hazardous reactions | : | Stable under recommended storage conditions.<br>No hazards to be specially mentioned. |
| Conditions to avoid | : | No data available |
| Incompatible materials | : | Not applicable |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

## SECTION 11. TOXICOLOGICAL INFORMATION

**Acute toxicity**
Not classified due to lack of data.

**Components:**

**Trastuzumab:**

| | | |
|---|---|---|
| Acute oral toxicity | : | Remarks: Not bioavailable by oral administration |
| Acute toxicity (other routes of administration) | : | Maximum tolerated dose (Mouse): > 94 mg/kg<br>Application Route: i.v. |

**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. |

**Serious eye damage/eye irritation**
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.

**Components:**

**Trastuzumab:**

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

**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. |

**Repeated dose toxicity**

**Components:**

**Hyaluronidase:**

| | | |
|---|---|---|
| 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:**

**Trastuzumab:**

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

**Endocrine disrupting properties**

**Components:**

**Trastuzumab:**

Assessment : Does not have endocrine disrupting properties.

**Hyaluronidase:**

Assessment : Does not have endocrine disrupting properties.

## SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Hyaluronidase:**

**Ecotoxicology Assessment**

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

Other organisms relevant to the environment : No data available

**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

**Hyaluronidase:**

Biodegradability : Result: Globular proteins are generally well biodegradable

**Bioaccumulative potential**

**Components:**

**Trastuzumab:**

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

**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).

Additional ecological information : No data available

**Components:**

**Trastuzumab:**

Results of PBT and vPvB assessment : Not persistent, bioaccumulative, and toxic (PBT).

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:**

Results of PBT and vPvB : Not persistent, bioaccumulative, and toxic (PBT).

assessment

Additional ecological information : No data available

**Endocrine disrupting properties**

**Components:**

**Trastuzumab:**
Assessment : Does not have endocrine disrupting properties.

**Hyaluronidase:**
Assessment : Does not have endocrine disrupting properties.

## 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 IMO instruments**
Not applicable

**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**

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

**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 SOCMI 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**

No components are subject to the Massachusetts Right to Know Act.

**Pennsylvania Right To Know**

| | |
|---|---|
| Water | 7732-18-5 |
| Trastuzumab | 180288-69-1 |
| Trehalose (D+)-), 2H2O | 6138-23-4 |

**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

**The ingredients of this product are reported in the following inventories:**

| | | |
|---|---|---|
| AU AIIC | : | Not in compliance with the inventory |
| CA. DSL | : | This product contains the following components that are not on the Canadian DSL nor NDSL. |
| | | Trastuzumab |
| | | L-Histidine monohydrochloride monohydrate |
| | | Hyaluronidase |
| NZ NZIoC | : | On the inventory, or in compliance with the inventory |
| JP ENCS | : | Not in compliance with the inventory |
| JP ISHL | : | Not in compliance with the inventory |
| KR KECI | : | Not in compliance with the inventory |

| | | |
|---|---|---|
| PH PICCS | : | Not in compliance with the inventory |
| CN IECSC | : | Not in compliance with the inventory |
| TW TCSI | : | Not in compliance with the inventory |
| US TSCA | : | Product contains substance(s) not listed on TSCA inventory. |
| TH 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**

## HERCEPTIN HYLECTA Vials 600 mg/5 ml

| Version | Revision Date: | Date of last issue: 06/14/2025 |
|---|---|---|
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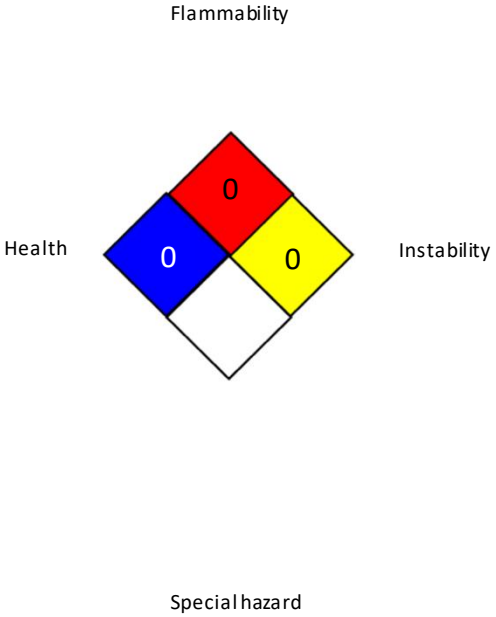
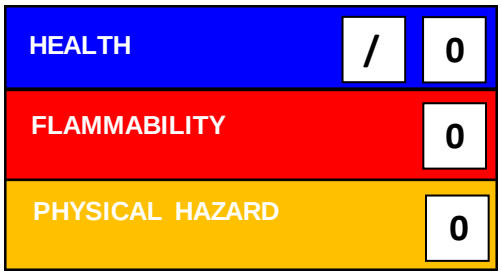
**NFPA 704:**




**HMIS® IV / CED:**




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**

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 Standardization; 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 Organization 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, Authorization 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 Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 09/02/2026

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 / EN / 2510