



## HERCEPTIN(R) Vials (440 mg)

### SECTION 3: Composition/information on ingredients

Characterization recombinant humanised monoclonal antibody (Trastuzumab) with excipients

Ingredients	Concentration
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Trastuzumab	51.4 %
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CAS: 180288-69-1	
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Trehalose dihydrate	46.7 %
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CAS: 6138-23-4	
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L-Histidine	0.74 %
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CAS: 71-00-1	
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L-Histidine hydrochloride monohydrate	1.15 %
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CAS: 5934-29-2	
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Polysorbate 20	0.01 %
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CAS: 9005-64-5	
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### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

Eye contact	- rinse immediately with tap water for 10 minutes - open eyelids forcibly
Skin contact	- remove contaminated clothes, wash affected skin with water and soap - do not use any solvents
Inhalation	- remove the casualty to fresh air and keep him/her calm - in the event of symptoms get medical treatment

#### 4.2. Most important symptoms and effects, both acute and delayed

Note	- no information available
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#### 4.3. Indication of any immediate medical attention and special treatment needed

Note to physician	- treat symptomatically
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### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media	- adapt extinguishing media to surrounding fire conditions
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Flash point (liquid)	not applicable
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## 5.2. Special hazards arising from the substance or mixture

Specific hazards - no particular hazards known

## 5.3. Advice for firefighters

Protection of fire-fighters - precipitate gases/vapours/mists with water spray

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions - no special precautions required

### 6.2. Environmental precautions

Environmental protection - no special environmental precautions required

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up - collect solids (avoid dust formation) and hand over to waste removal  
- flush afterwards with plenty of water

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Suitable materials - glass

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - 2 - 8 °C  
- protected from light  
- do not freeze following reconstitution or dilution

Validity - 2 to 8 °C, in the unopened original container, see "best use before" date stated on the label

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.1 mg/m<sup>3</sup> \*1

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## 8.2. Exposure controls

- Respiratory protection
- Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.
  - respiratory protection not necessary during normal operations
  - breathing apparatus in case of aerosol mist formation
- Hand protection
- protective gloves (eg made of neoprene, nitrile or butyl rubber)
- Eye protection
- safety glasses

\*1 referring to: Trastuzumab

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

- Color
- white to slightly yellow
- Form
- lyophilized powder
- pH value
- 5.4 to 6.6
- \*2

### 9.2. Other information

- Note
- no information available

\*2 referring to: Herceptin Vials (2% Trastuzumab solution with excipients)

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

- Note
- no information available

### 10.2. Chemical stability

- Stability
- does not contain any antimicrobial preservative; therefore, care must be taken to ensure the sterility of the prepared solution \*2
  - do not dilute with glucose since there cause aggregation of the protein \*2
  - do not freeze the reconstituted solution \*2

### 10.3. Possibility of hazardous reactions

- Note
- no information available

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### 10.4. Conditions to avoid

Conditions to avoid - warming

### 10.5. Incompatible materials

Note - no information available

### 10.6. Hazardous decomposition products

Note - do not shake the solution, formation of foam \*2

\*2 referring to: Herceptin Vials (2% Trastuzumab solution with excipients)

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity	- MTD	> 94	mg/kg	(i.v., mouse)	*1
	- MTD	> 47	mg/kg	(i.v., Rhesus monkey)	*1
	- LD <sub>50</sub>	> 5'110	mg/kg	(oral, rat)	*3
	- TD <sub>10</sub>	16'000	mg/kg	(oral, rat)	*4

Sensitization - anaphylactic reactions may occur following the intravenous application of proteins; rare cases of hypersensitivity have been described \*1

Reproductive toxicity - parenteral administration to pregnant women can cause fetal harm\*1

Note

- infusions should not be administered through IV line containing dextrose solutions
- Trastuzumab is a humanized monoclonal antibody that targets selectively the extracellular domain of the human epidermal growth factor receptor (HER2) \*1
- elimination half-life (after multiple dose): 1.7 to 32.8 days \*1
- Herceptin administration (in therapeutic doses) can result in the development of ventricular dysfunction and congestive heart failure. \*5
- side effect(s) during therapy: dyspnea, hypotension, tachycardia, bronchospasm, wheezing, reduced oxygen saturation \*5

Potential Health Effects

- Exposure: Inhalation, Ingestion, Skin contact, Eye contact
- Carcinogenicity: formulation not listed by NTP, IARC or OSHA

\*1 referring to: Trastuzumab

\*3 referring to: L-Histidine

\*4 referring to: Trehalose dihydrate

\*5 referring to: Diluted Herceptin infusion solution (approx. 0.06% Trastuzumab)

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## SECTION 12: Ecological information

### 12.1. Toxicity

Ecotoxicity - monoclonal antibodies are proteins with highly specific affinity to a certain antigen; therefore, no appreciable ecotoxic potential is to be expected

\*1

### 12.2. Persistence and degradability

Ready biodegradability - globular proteins are generally well biodegradable

\*1

### 12.3. Bioaccumulative potential

Note - no information available

### 12.4. Mobility in soil

Note - no information available

### 12.5. Results of PBT and vPvB assessment

Note - no information available

### 12.6. Other adverse effects

Note - no information available

\*1 referring to: Trastuzumab

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste from residues - observe local/national regulations regarding waste disposal  
- drain very small quantities into wastewater treatment plant

## SECTION 14: Transport information

Note - not classified by transport regulations, proper shipping name non-regulated

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

TSCA Status - FDA Exemption - not on inventory

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### Reporting Requirements

- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
- In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.
- State and local regulations vary and may impose additional reporting requirements.

## SECTION 16: Other information

### Edition documentation

- changes from previous version in sections 2, 5, 6, 8, 10, 11

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.