SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name          HERCEPTIN HYLECTATM Vials (600 mg/5 ml) SC
Product code          SAP-10112127
Synonyms              - Herceptin Hylecta SC
                         - Herceptin Hylecta s.c. 120 mg/ml
                         - MAB<HER2>SC-rH-13-10-IgG

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use                   - pharmaceutical active substance (antineoplastic) *1
                         - active substance in Herceptin *1

1.3. Details of the supplier of the safety data sheet

Company information   Enquiries: Genentech, Inc.
                         1 DNA Way
                         South San Francisco
                         USA-CA 94080
                         United States of America

                         Phone   001-(650) 225-1000
                         E-Mail   info.sds@roche.com
                         US Chemtrec phone: (800)-424-9300

Local representation:

1.4. Emergency telephone number

Emergency telephone number  US Chemtrec phone: (800)-424-9300

*1 referring to: Trastuzumab

SECTION 2: Hazards identification

Classification of the substance or mixture / Label elements

GHS Classification       no classification and labelling according to GHS

Other hazards

Note                   - no information available
SECTION 3: Composition/information on ingredients

Characterization
solution of Trastuzumab with excipients for subcutaneous injection

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trastuzumab</td>
<td>12 %</td>
<td></td>
</tr>
<tr>
<td>180288-69-1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hyaluronidase (rHuPH20)</td>
<td>0.004 %</td>
<td></td>
</tr>
<tr>
<td>757971-58-7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trehalose dihydrate</td>
<td>8 %</td>
<td></td>
</tr>
<tr>
<td>6138-23-4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact
- rinse with tap water for 20 minutes - open eyelids forcibly

Skin contact
- drench affected skin with water

Inhalation
- in the event of symptoms get medical treatment

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

Note
- no information available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physician
- treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media
- adapt extinguishing media to surrounding fire conditions

Flash point (liquid)
not applicable

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 - mop or flush the contaminated area with 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
- do not freeze

Validity - 18 months, 2 to 8 °C, after opening the content should be used within a short period, see expiry date on the label, in the unopened original container

Packaging materials - vials
- keep it in the outer carton in order to protect from light

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.1 mg/m³

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

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>colorless to slightly yellow</td>
</tr>
<tr>
<td></td>
<td>clear to opalescent</td>
</tr>
<tr>
<td>Form</td>
<td>liquid</td>
</tr>
<tr>
<td>pH value</td>
<td>5.5</td>
</tr>
</tbody>
</table>

9.2. Other information

Note - no information available

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
- once transferred from the vial to the syringe, the product is physically and chemically stable at 2 to 8°C for 24 hours

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Conditions to avoid - warming
- light

10.5. Incompatible materials

Note - no information available

10.6. Hazardous decomposition products

Note - no information available
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

Local effects
assessment of local tolerance after a single subcutaneous application of 60 mg/injection site (0.5 mL/injection site) showed no findings that were attributable to treatment with the test item (rabbit)

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

Mutagenicity
- no information available

Carcinogenicity
- no information available

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

STOT-single exposure
- no information available

STOT-repeated exposure
- no information available

Aspiration hazard
- no information available

Note
- 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

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

*1 referring to: Trastuzumab

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
- readily biodegradable
  65 % BOD/ThOD, 14 d (Manometric Respirometry Test, OECD No. 301 F) *1
HERCEPTIN HYLECTA™ Vials (600 mg/5 ml) SC

- readily biodegradable
  87 % BOD/ThOD, 14 d
  (Manometric Respirometry Test, OECD No. 301 F)

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
*2 referring to: Trastuzumab 2.4% solution with excipients

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - observe local/national regulations regarding waste disposal
  - drain into sewer

SECTION 14: Transport information

Note - not classified as Dangerous Good according to the Dangerous Goods 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

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 and to local officials.
  - State and local regulations vary and may impose additional reporting requirements.
### SECTION 16: Other information

**Note**  
- contains 2000 U/ml hyaluronidase; corresponds to 0.173 mg rHuPH20 (highest theoretical amount)  
- Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user.

**Edition documentation**  
- changes from previous version in sections 1, 3

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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.