SECTION 1. IDENTIFICATION

Product name : PERJETA(R) (420 mg)
Product code : 00010113898
Common name(s), synonym(s) of the substance : Pertuzumab 3.0 % aqueous solution 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 number : US Chemtrec phone (800)-424-9300

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
<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pertuzumab</td>
<td>380610-27-5</td>
<td>3.0</td>
</tr>
<tr>
<td>.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl</td>
<td>57-50-1</td>
<td>4.11</td>
</tr>
<tr>
<td>L-Histidine</td>
<td>71-00-1</td>
<td>0.31</td>
</tr>
<tr>
<td>Acetic acid</td>
<td>64-19-7</td>
<td>0.07</td>
</tr>
<tr>
<td>Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.</td>
<td>9005-64-5</td>
<td>0.02</td>
</tr>
</tbody>
</table>
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 firefighting:
- No information available.

Hazardous combustion products:
- In case of fire hazardous decomposition products may be produced such as:
  - Carbon monoxide
  - Nitrogen oxides (NOx)

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
SAFETY DATA SHEET

PERJETA(R) (420 mg)

Version 0.0
Revision Date: 01-23-2020
Date of last issue: 06-10-2017
Date of first issue: 05-10-2016

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

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

Methods and materials for containment and cleaning up:
Wipe up with absorbent material (e.g. cloth, fleece).
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. 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.

Further information on storage conditions:
See label, package insert or internal guidelines

Materials to avoid:
No materials to be especially mentioned.

Storage temperature:
Protected from heat and light

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

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl</td>
<td>57-50-1</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m3</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m3</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>15 mg/m3</td>
<td>OSHA P0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respir-)</td>
<td>5 mg/m3</td>
<td>OSHA P0</td>
</tr>
</tbody>
</table>
**SAFETY DATA SHEET**

**PERJETA(R) (420 mg)**

<table>
<thead>
<tr>
<th>Name</th>
<th>CAS Number</th>
<th>TWA</th>
<th>STEL</th>
<th>NIOSH REL</th>
<th>OSHA Z-1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pertuzumab</td>
<td>380610-27-5</td>
<td>10 ppm</td>
<td>15 ppm</td>
<td>15 ppm</td>
<td>15 ppm</td>
</tr>
<tr>
<td>Acetic acid</td>
<td>64-19-7</td>
<td>10 ppm</td>
<td>15 ppm</td>
<td>10 ppm</td>
<td>10 ppm</td>
</tr>
</tbody>
</table>

**Engineering measures**: No data available

**Personal protective equipment**

**Respiratory protection**: No personal respiratory protective equipment normally required.

**Hand protection**

**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.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**: Aqueous solution, Clear liquid, sterile

**Color**: Colorless, light brown

**Odor**: No data available

**Odor Threshold**: No data available

**pH**: No data available

**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 : No data available
Relative density : No data available
Density : 1.03 g/cm³ (20 °C / 20 °C)
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

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.
SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Not classified based on available information.

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:
Acute oral toxicity : LD50 Oral (Rat): 29,700 mg/kg
                 : LD50 Oral (Mouse): 14,000 mg/kg
Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l
                          : Test atmosphere: dust/mist
                          : Method: Expert judgment
Acute dermal toxicity  : Acute toxicity estimate: > 5,001 mg/kg
                         : Method: Expert judgment

Pertuzumab:
Acute oral toxicity : Remarks: Not bioavailable by oral administration

Acetic acid:
Acute oral toxicity : LD50 Oral (Rat): 3,310 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:

Acetic acid:
Species : Rabbit
Result   : Causes severe burns.

Serious eye damage/eye irritation
Not classified based on available information.

Components:

Acetic acid:
Species : Rabbit
Result   : Risk of serious damage to eyes.
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.

Components:

**Acetic acid:**
Genotoxicity in vitro: Test Type: Ames test
Method: Mutagenicity (Salmonella typhimurium - reverse mutation assay)
Result: negative
Remarks: In vitro tests did not show mutagenic effects

Method: OECD Test Guideline 473
Remarks: In vitro tests did not show mutagenic effects

Germ cell mutagenicity - Assessment: Not mutagenic in Ames Test.

Carcinogenicity
Not classified based on available information.

Components:

**.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**
Remarks: 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.

**Acetic acid:**
Remarks: 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.

**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.

**STOT-single exposure**
Not classified based on available information.
Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:
Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure
Not classified based on available information.

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:
Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Repeated dose toxicity

Components:

Pertuzumab:
Species: cynomolgus monkey
NOAEL: mg/kg/w, 250
Application Route: s.c.
Exposure time: 4 Weeks
GLP: yes
Remarks: Subacute toxicity

Species: cynomolgus monkey
Application Route: i.v.
Exposure time: 26 Weeks
GLP: yes
Remarks: Subchronic toxicity

Aspiration toxicity
Not classified based on available information.

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:
No data available

Further information

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:
Remarks: Health injuries are not known or expected under normal use.

Pertuzumab:
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

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Toxicity to fish : LC₅₀: > 100 mg/l
Exposure time: 96 h

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

Acetic acid:

Toxicity to fish : LC₅₀ (Leuciscus idus (Golden orfe)): 410 mg/l
Exposure time: 48 h

NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

LC₅₀ (Oncorhynchus mykiss (rainbow trout)): 160 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 203

LC₁₀₀ (Oncorhynchus mykiss (rainbow trout)): 500 mg/l
Exposure time: 48 h

LC₀ (Oncorhynchus mykiss (rainbow trout)): 50 mg/l
Exposure time: 48 h

LC₅₀ (Lepomis macrochirus (Bluegill sunfish)): 75 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC₅₀ (Daphnia magna (Water flea)): 95 mg/l
Exposure time: 24 h

EC₅₀ (Daphnia magna (Water flea)): > 1,000 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Persistence and degradability

Components:

Pertuzumab:
Biodegradability: Result: Globular proteins are generally well biodegradable

**Acetic acid:**

Biodegradability: Zahn-Wellens Test  
Concentration: 1,250 mg/l  
Result: Readily biodegradable.  
Biodegradation: 99%  
Exposure time: 5 d  
Method: OECD Test Guideline 302B

Zahn-Wellens Test  
Concentration: 1,250 mg/l  
Result: Readily biodegradable.  
Biodegradation: 91%  
Exposure time: 1 d  
Method: OECD Test Guideline 302B

Result: Readily biodegradable.  
Biodegradation: 71%  
Exposure time: 5 d

**Bioaccumulative potential**

**Components:**

**.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

Partition coefficient: n-octanol/water: log Pow: -3.67

**Pertuzumab:**

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

**Acetic acid:**

Bioaccumulation: Bioconcentration factor (BCF): 3.16

Partition coefficient: n-octanol/water: log Pow: -0.17 (25 °C / 25 °C)  
pH: 7

**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:

Pertuzumab:
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.

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
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component RQ (lbs)</th>
<th>Calculated product RQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetic acid</td>
<td>64-19-7</td>
<td>5000</td>
<td>*</td>
</tr>
</tbody>
</table>

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.
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SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component TPQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARA 311/312 Hazards</td>
<td></td>
<td>No SARA Hazards</td>
</tr>
</tbody>
</table>

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
The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:
- Acetic acid 64-19-7 >= 0 - < 0.1 %
The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:
- Acetic acid 64-19-7 >= 0 - < 0.1 %
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know
/alpha.-D-Glucopyranoside, beta.-D-fructofuranosyl 57-50-1

Pennsylvania Right To Know
- Water 7732-18-5
- /alpha.-D-Glucopyranoside, beta.-D-fructofuranosyl 57-50-1
- Pertuzumab 380610-27-5
- Acetic acid 64-19-7

Maine Chemicals of High Concern

Vermont Chemicals of High Concern

Washington Chemicals of High Concern

California Permissible Exposure Limits for Chemical Contaminants
/alpha.-D-Glucopyranoside, beta.-D-fructofuranosyl 57-50-1

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.
  - Pertuzumab
- 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
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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

NFPA: Flammability
Health 0 0 0
Instability
Special hazard

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

ACGIH: USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL: USA. NIOSH Recommended Exposure Limits
OSHA P0: USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
OSHA Z-1: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA: 8-hour, time-weighted average
ACGIH / STEL: Short-term exposure limit
NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / ST: STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
OSHA P0 / TWA: 8-hour time weighted average
OSHA Z-1 / TWA: 8-hour time weighted average
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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.

US / Z8 / 1810