

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

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

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) |
|---|-------------|-----------------------|
| Pertuzumab | 380610-27-5 | 3.0 |
| .alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl | 57-50-1 | 4.11 |
| L-Histidine | 71-00-1 | 0.31 |
| Acetic acid | 64-19-7 | 0.07 |
| Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs. | 9005-64-5 | 0.02 |

PERJETA(R) (420 mg)

Version
0.0

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Date of last issue: 06-10-2017
Date of first issue: 05-10-2016

| | | |
|-------|-----------|-------|
| Water | 7732-18-5 | 92.49 |
|-------|-----------|-------|

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 : 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

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- 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

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---|---------|-------------------------------|--|-----------|
| .alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl | 57-50-1 | TWA | 10 mg/m3 | ACGIH |
| | | TWA (Respirable) | 5 mg/m3 | NIOSH REL |
| | | TWA (total) | 10 mg/m3 | NIOSH REL |
| | | TWA (total dust) | 15 mg/m3 | OSHA Z-1 |
| | | TWA (respirable fraction) | 5 mg/m3 | OSHA Z-1 |
| | | TWA (Total dust) | 15 mg/m3 | OSHA P0 |
| | | TWA (respir- | 5 mg/m3 | OSHA P0 |

SAFETY DATA SHEET

PERJETA(R) (420 mg)

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| | | able dust fraction) | | |
|-------------|-------------|---------------------|--------------------|---|
| Pertuzumab | 380610-27-5 | IOEL | 0.04 mg/m3 | Roche Industrial Hygiene Committee (RIHC) |
| Acetic acid | 64-19-7 | TWA | 10 ppm | ACGIH |
| | | STEL | 15 ppm | ACGIH |
| | | TWA | 10 ppm 25 mg/m3 | NIOSH REL |
| | | ST | 15 ppm 37 mg/m3 | NIOSH REL |
| | | TWA | 10 ppm 25 mg/m3 | OSHA Z-1 |
| | | TWA | 10 ppm 25 mg/m3 | OSHA P0 |

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.

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

SAFETY DATA SHEET

PERJETA(R) (420 mg)

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| | | |
|--|---|--|
| 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/cm ³ (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. |

PERJETA(R) (420 mg)

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0.0

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01-23-2020

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Conditions to avoid : No data available
Incompatible materials : No data available
Hazardous decomposition products : No data available

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.

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

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.

PERJETA(R) (420 mg)Version
0.0Revision Date:
01-23-2020Date of last issue: 06-10-2017
Date of first issue: 05-10-2016**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 toxicitySpecies : cynomolgus monkey
: 50 mg/kg/w
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

PERJETA(R) (420 mg)Version
0.0Revision Date:
01-23-2020Date of last issue: 06-10-2017
Date of first issue: 05-10-2016**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 hNOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203LC50 (Oncorhynchus mykiss (rainbow trout)): 160 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 203LC100 (Oncorhynchus mykiss (rainbow trout)): 500 mg/l
Exposure time: 48 hLC0 (Oncorhynchus mykiss (rainbow trout)): 50 mg/l
Exposure time: 48 hLC50 (Lepomis macrochirus (Bluegill sunfish)): 75 mg/l
Exposure time: 96 hToxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 95 mg/l
Exposure time: 24 hEC50 (Daphnia magna (Water flea)): > 1,000 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202**Persistence and degradability****Components:****Pertuzumab:**

PERJETA(R) (420 mg)Version
0.0Revision Date:
01-23-2020Date of last issue: 06-10-2017
Date of first issue: 05-10-2016

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 302BZahn-Wellens Test
Concentration: 1,250 mg/l
Result: Readily biodegradable.
Biodegradation: 91 %
Exposure time: 1 d
Method: OECD Test Guideline 302BResult: 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 Pro-
tection of Stratospheric Ozone - CAA Section 602 Class I
Substances
Remarks: This product neither contains, nor was manufac-
tured 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).

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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

| Components | CAS-No. | Component RQ (lbs) | Calculated product RQ (lbs) |
|-------------|---------|--------------------|-----------------------------|
| Acetic acid | 64-19-7 | 5000 | * |

*: 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.

SAFETY DATA SHEET

PERJETA(R) (420 mg)

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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

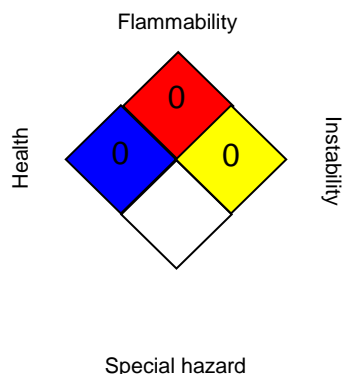
TSCA list

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:



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

PERJETA(R) (420 mg)Version
0.0Revision Date:
01-23-2020Date of last issue: 06-10-2017
Date of first issue: 05-10-2016

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; IECS - 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

Revision Date : 01-23-2020

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