

Safety Data Sheet

# PHESGO™ (pertuzumab, trastuzumab & hyaluronidase-zzxf) Injection (80 mg/ml, 40 mg/ml)

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

### 1.1. Product identifier

Product name	PHESGO™ (pertuzumab, trastuzumab & hyaluronidase-zzxf) Injection (80 mg/ml, 40 mg/ml)	
Product code	RO719-8574-F03	
Roche number	RO0452317-000	*1
	RO4368451-000	*2
	RO5221651-000	*3
Synonyms	- Trastuzumab, Pertuzumab Fixed Dose Combination (40mg/ml, 80mg/ml) Loading Dose	
	- pertuzumab, trastuzumab & hyaluronidase Injection (80 mg/ml, 40 mg/ml)	
	- HERCEPTIN® SC (Trastuzumab)*1, PERJETA® SC (Pertuzumab)*2	
	HER2 (human epidermal growth factor receptor 2 protein)	*1
	rhuMAb 2C4	*2
	36-482-Hyaluronoglucosaminidase PH20 (human)	*3

### 1.3. Details of the supplier of the safety data sheet

Company information	Enquiries:	Local representation:
	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

### 1.4. Emergency telephone number

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

*1	referring to:	Trastuzumab
*2	referring to:	Pertuzumab
*3	referring to:	Hyaluronidase (rHuPH20)

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**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                      recombinant humanized monoclonal antibody                      \*1  
recombinant humanized monoclonal antibody                      \*2  
glycosylated polypeptide with 447 amino acids                      \*3

<b>Ingredients</b>	<b>Concentration</b>	<b>GHS-Classification (pure ingredient)</b>
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Trastuzumab  
180288-69-1

4 %

Pertuzumab  
380610-27-5

8 %

Hyaluronidase (rHuPH20)  
757971-58-7

0.003 %

Sucrose  
57-50-1

4.564 %

\*1 referring to:                      Trastuzumab  
\*2 referring to:                      Pertuzumab  
\*3 referring to:                      Hyaluronidase (rHuPH20)

**SECTION 4: First aid measures**

**4.1. Description of first aid measures**

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

Skin contact                                      - remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents

Inhalation    - remove the casualty to fresh air  
- 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

**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 - collect liquids by means of sand, earth or another suitable material  
- flush afterwards with plenty of water

**SECTION 7: Handling and storage**

**7.1. Precautions for safe handling**

Suitable materials - PVC, polyethylene, glass

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

Storage conditions - 2 - 8 °C  
- keep container tightly closed  
- protected from light

Packaging materials - vials

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## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Threshold value (USA) air	- ACGIH-TLV: 10 mg/m <sup>3</sup>	*4
	- OSHA-PEL: 5 mg/m <sup>3</sup> (respirable fraction)	*4
	- OSHA-PEL: 15 mg/m <sup>3</sup> (total dust)	*4
	- NIOSH-REL: 5 mg/m <sup>3</sup> (respirable fraction)	*4
	- NIOSH-REL: 10 mg/m <sup>3</sup> (total dust)	*4

Threshold value (Roche) air	- IOEL (Internal Occupational Exposure Limit): 0.1 mg/m <sup>3</sup>	*1
	- IOEL (Internal Occupational Exposure Limit): 0.04 mg/m <sup>3</sup>	*2
	- IOEL (Internal Occupational Exposure Limit): 60 mg/m <sup>3</sup>	*3

### 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
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Hand protection	- protective gloves (eg made of neoprene, nitrile or butyl rubber)
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Eye protection	- safety glasses
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*1 referring to:	Trastuzumab
*2 referring to:	Pertuzumab
*3 referring to:	Hyaluronidase (rHuPH20)
*4 referring to:	Sucrose

## SECTION 9: Physical and chemical properties

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

Color	colorless
Form	liquid
pH value	5.2 to 5.8

### 9.2. Other information

Note	- no information available
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## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Note	- no information available
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**10.2. Chemical stability**

Stability - does not contain any antimicrobial preservative; therefore, care must be taken to ensure the sterility of the prepared solution

**10.3. Possibility of hazardous reactions**

Note - no information available

**10.4. Conditions to avoid**

Note - no information available

**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
	- not bioavailable by oral administration	*1
	- not bioavailable by oral administration	*2
	- not bioavailable by oral administration	*3
Subacute toxicity	- NOAEL 250 mg/kg/w (s.c., cynomolgus monkey, 4 weeks)	*2
Subchronic toxicity	- LD <sub>50</sub> 50 mg/kg/w (i.v., cynomolgus monkey; 26 weeks)	*2
	- NOAEL 2 mg/kg/w (s.c., cynomolgus monkey; 39 weeks)	*3
Local effects	- no information available	
Sensitization	anaphylactic reactions may occur following the application of proteins; rare cases of hypersensitivity have been described	*1
	anaphylactic reactions may occur following the intravenous application of proteins; rare cases of hypersensitivity have been described with other monoclonal antibodies	*2
	with enzymes, repeated inhalation of dust or aerosols as well as direct contact may cause sensitization and allergic reactions in predisposed individuals	*3
Mutagenicity	- no information available	
Carcinogenicity	- no information available	
Reproductive toxicity	- parenteral administration to pregnant women can cause fetal harm	*1

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STOT-single exposure	- no information available	
STOT-repeated exposure	- no information available	
Aspiration hazard	- no information available	
Note	- Herceptin administration (in therapeutic doses) can result in the development of ventricular dysfunction and congestive heart failure.	*1
	- 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	
*2 referring to:	Pertuzumab	
*3 referring to:	Hyaluronidase (rHuPH20)	

**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
	- monoclonal antibodies are proteins with highly specific affinity to a certain antigen; therefore, no appreciable ecotoxic potential is to be expected	*2

**12.2. Persistence and degradability**

Ready biodegradability	- readily biodegradable 65 % BOD/ThOD, 14 d (Manometric Respirometry Test, OECD No. 301 F)	*1
	- globular proteins are generally well biodegradable	*2
	- globular proteins are generally well biodegradable	*3

**12.3. Bioaccumulative potential**

Note	- no information available
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**12.4. Mobility in soil**

Note	- no information available
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## 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: Pertuzumab  
\*3 referring to: Hyaluronidase (rHuPH20)

## 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 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 - none

Edition documentation - changes from previous version in sections 3, 7

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.