

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pertuzumab Biosimilar Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	11/24/2025	310000001697	Date of first issue: 11/24/2025

### SECTION 1. IDENTIFICATION

Product name : Pertuzumab Biosimilar Formulation  
Other means of identification : Prescription Medicine

#### Manufacturer or supplier's details

Company name of supplier : Organon & Co.  
Address : 30 Hudson Street, 33rd floor  
Jersey City, New Jersey 07302

Telephone : +1 551-430-6000 US  
Emergency telephone : For 24/7 emergency response advice, call CHEMTREC at +1 703-741-5970 (Regional). Global 24/7: +1-800-424-9300 (United States, English only).

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical  
Restrictions on use : To be dispensed by or on the prescription of physician.

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Specific target organ toxicity : Category 2 (Gastrointestinal tract, Kidney)  
- repeated exposure

#### GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H373 May cause damage to organs (Gastrointestinal tract, Kidney) through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**  
P260 Do not breathe mist or vapors.  
**Response:**  
P314 Get medical advice/ attention if you feel unwell.  
**Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pertuzumab Biosimilar Formulation

Version 1.0      Revision Date: 11/24/2025      SDS Number: 310000001697      Date of last issue: -  
Date of first issue: 11/24/2025

### Other hazards

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Pertuzumab	Pertuzumab	380610-27-5	3

## SECTION 4. FIRST AID MEASURES

If inhaled : If inhaled, remove to fresh air.  
Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap as a precaution.  
Get medical attention if symptoms occur.

In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention if symptoms occur.  
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : Reference Section 11: Experience with human exposure.  
May cause damage to organs through prolonged or repeated exposure.

Protection of first-aiders : No special precautions are necessary for first aid responders.

Notes to physician : Treat symptomatically and supportively.

## SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Sulfur oxides  
Nitrogen oxides (NO<sub>x</sub>)  
  
Water

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.



# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pertuzumab Biosimilar Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	11/24/2025	310000001697	Date of first issue: 11/24/2025

Use a water spray to cool fully closed containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.  
Use personal protective equipment.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage.  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Clean thoroughly.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : See current prescribing information.  
Store in original container.  
Refrigeration required (2 - 8°C).  
Do not freeze.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pertuzumab Biosimilar Formulation

Version 1.0      Revision Date: 11/24/2025      SDS Number: 310000001697      Date of last issue: -  
Date of first issue: 11/24/2025

Materials to avoid : Do not shake.  
: Do not store with the following product types:  
Strong oxidizing agents  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Pertuzumab	380610-27-5	TWA	1300 µg/m <sup>3</sup> (OEB 1)	Internal

**Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

#### Personal protective equipment

**Respiratory protection** : No personal respiratory protective equipment normally required.  
If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

**Hand protection**  
**Material** : Chemical-resistant gloves

**Eye protection** : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and body protection** : Work uniform or laboratory coat.  
**Hygiene measures** : The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.  
If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution



# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pertuzumab Biosimilar Formulation

Version 1.0	Revision Date: 11/24/2025	SDS Number: 310000001697	Date of last issue: - Date of first issue: 11/24/2025
----------------	------------------------------	-----------------------------	----------------------------------------------------------

Color	:	Colorless to pale yellow
Odor	:	odorless
pH	:	6
Melting point/freezing point	:	Not applicable
Boiling point/boiling range	:	not determined
Flash point	:	Not applicable
Flammability (liquids)	:	Will not burn
Upper explosion limit / Upper flammability limit	:	Not applicable
Lower explosion limit / Lower flammability limit	:	Not applicable
Vapor pressure	:	not determined
Relative vapor density	:	not determined
Density	:	similar to water not determined
Solubility(ies) Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	does not ignite
		Not applicable
Viscosity Viscosity, dynamic	:	not determined

### SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pertuzumab Biosimilar Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	11/24/2025	310000001697	Date of first issue: 11/24/2025

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Acute toxicity

Not classified due to lack of data.

#### Components:

##### Pertuzumab:

Acute oral toxicity : Remarks: No data available

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : Remarks: No data available

#### Skin corrosion/irritation

Not classified due to lack of data.

#### Components:

##### Pertuzumab:

Remarks : No data available

#### Serious eye damage/eye irritation

Not classified due to lack of data.

#### Components:

##### Pertuzumab:

Remarks : No data available

#### Respiratory or skin sensitization

##### Skin sensitization

Not classified due to lack of data.

##### Respiratory sensitization

Not classified due to lack of data.

#### Components:

##### Pertuzumab:

Test Type : Skin sensitization  
Assessment : Not classified  
Remarks : No data available

Test Type : Respiratory sensitization  
Assessment : Not classified  
Remarks : No data available

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pertuzumab Biosimilar Formulation

Version 1.0	Revision Date: 11/24/2025	SDS Number: 310000001697	Date of last issue: - Date of first issue: 11/24/2025
----------------	------------------------------	-----------------------------	----------------------------------------------------------

As a class, protein-based therapeutics have been shown to have the potential to cause respiratory sensitization

### Germ cell mutagenicity

Not classified due to lack of data.

#### Components:

##### **Pertuzumab:**

Genotoxicity in vitro	:	Remarks: Not classified
Genotoxicity in vivo	:	Remarks: Not classified
Germ cell mutagenicity - Assessment	:	Weight of evidence does not support classification as a germ cell mutagen., Based on the size and properties of the material (monoclonal antibody), there is not potential to be a direct-acting mutagen.

### Carcinogenicity

Not classified due to lack of data.

#### Components:

##### **Pertuzumab:**

Remarks	:	Not classified
Carcinogenicity - Assessment	:	Not classified, Based on the size and properties of the material (monoclonal antibody), there is not potential to be a direct-acting carcinogen.

### Reproductive toxicity

Not classified based on available information.

#### Components:

##### **Pertuzumab:**

Effects on fertility	:	Remarks: No data available
Effects on fetal development	:	Test Type: One-generation reproduction toxicity study Species: Monkey Application Route: Intravenous Frequency of Treatment: 1 daily General Toxicity Maternal: NOAEL: 100 mg/kg body weight Embryo-fetal toxicity.: LOAEL: 10 mg/kg body weight Symptoms: Embryo-lethal effects., Specific developmental abnormalities. Target Organs: Kidney Result: Embryo-lethal effects., Specific developmental abnormalities.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pertuzumab Biosimilar Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	11/24/2025	310000001697	Date of first issue: 11/24/2025

---

### STOT-single exposure

Not classified due to lack of data.

### STOT-repeated exposure

May cause damage to organs (Gastrointestinal tract, Kidney) through prolonged or repeated exposure.

### Components:

#### Pertuzumab:

Target Organs	:	Gastrointestinal tract, Kidney
Assessment	:	May cause damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

### Components:

#### Pertuzumab:

Species	:	Monkey
LOAEL	:	15 mg/kg
Application Route	:	Intravenous
Exposure time	:	26 weeks
Number of exposures	:	weekly
Target Organs	:	Gastrointestinal tract, Kidney
Symptoms	:	diarrhea, Dehydration

### Aspiration toxicity

Not classified based on available information.

### Components:

#### Pertuzumab:

Not applicable

### Experience with human exposure

### Product:

General Information	:	Symptoms: diarrhea, nausea, Vomiting, joint pain, muscle weakness, decrease in appetite, breathing difficulties, fatigue, rash, Itching
---------------------	---	-----------------------------------------------------------------------------------------------------------------------------------------



# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pertuzumab Biosimilar Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	11/24/2025	310000001697	Date of first issue: 11/24/2025

### SECTION 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

##### **Pertuzumab:**

#### Ecotoxicology Assessment

Acute aquatic toxicity : No data available  
Remarks: Not classified

Chronic aquatic toxicity : No data available  
Remarks: Not classified

#### Persistence and degradability

##### Components:

##### **Pertuzumab:**

Biodegradability : Remarks: Expected to be biodegradable

#### Bioaccumulative potential

No data available

#### Mobility in soil

No data available

#### Other adverse effects

No data available

### SECTION 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

### 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

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pertuzumab Biosimilar Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	11/24/2025	310000001697	Date of first issue: 11/24/2025

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Domestic regulation

#### TDG

Not regulated as a dangerous good

### Special precautions for user

Not applicable

## SECTION 15. REGULATORY INFORMATION

### The ingredients of this product are reported in the following inventories:

AICS : All ingredients listed or exempt.

CA. DSL : All ingredients listed or exempt.

IECSC : All ingredients listed or exempt.

EINECS : All ingredients listed or exempt.

TSCA : All ingredients listed or exempt.

ENCS : All ingredients listed or exempt.

## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardization; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; 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; IECSC - 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 Organization 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; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pertuzumab Biosimilar Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	11/24/2025	310000001697	Date of first issue: 11/24/2025

---

Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals 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; WHMIS - Workplace Hazardous Materials Information System

Revision Date : 11/24/2025  
Date format : mm/dd/yyyy

The information provided in this 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.

CA / EN