

SAFETY DATA SHEET



Pembrolizumab / Berahyaluronidase alfa Subcutaneous Formulation

Version Revision Date: SDS Number: Date of last issue: 14.04.2025
5.1 15.10.2025 7723970-00018 Date of first issue: 06.01.2021

Section 1: Identification

Product identifier : Pembrolizumab / Berahyaluronidase alfa Subcutaneous Formulation

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

Manufacturer or supplier's details

Section 2: Hazard identification

Classification of the substance or mixture

Reproductive toxicity : Category 1B

Specific target organ toxicity - : Category 1 (Immune system)
repeated exposure (Oral)

GHS Label elements, including precautionary statements

Hazard pictograms



Signal word : Danger

Hazard statements : H360D May damage the unborn child.
H372 Causes damage to organs (Immune system) through prolonged or repeated exposure if swallowed.

Precautionary statements	:	Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe mist or vapours.
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Pembrolizumab / Berahyaluronidase alfa Sub-cutaneous FormulationVersion
5.1Revision Date:
15.10.2025SDS Number:
7723970-00018Date of last issue: 14.04.2025
Date of first issue: 06.01.2021

P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Pembrolizumab	1374853-91-4	>= 10 -< 20
Sucrose	57-50-1	>= 1 -< 10
Berahyaluronidase alfa	2636716-20-4	< 0.1

Section 4: First-aid measures**Description of necessary first-aid measures**

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

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

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

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.
Rinse mouth thoroughly with water.

SAFETY DATA SHEET



Pembrolizumab / Berahyaluronidase alfa Sub-cutaneous Formulation

Version
5.1

Revision Date:
15.10.2025

SDS Number:
7723970-00018

Date of last issue: 14.04.2025
Date of first issue: 06.01.2021

Most important symptoms and effects, both acute and delayed

Risks : May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure if swallowed.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

Special hazards arising from the substance or mixture

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

Hazardous combustion products : Carbon oxides

Special protective actions for fire-fighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

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

Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.

Pembrolizumab / Berahyaluronidase alfa Sub-cutaneous Formulation

Version 5.1	Revision Date: 15.10.2025	SDS Number: 7723970-00018	Date of last issue: 14.04.2025 Date of first issue: 06.01.2021
----------------	------------------------------	------------------------------	---

Prevent spreading over a wide area (e.g. by containment or oil barriers).

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

Methods for cleaning up : Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. 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**Precautions for safe handling**

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

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.
Do not breathe mist or vapours.
Do not swallow.
Avoid contact with eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : 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.
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.

Conditions for safe storage, including any incompatibilities

Conditions for safe storage : Keep in properly labelled containers.

Pembrolizumab / Berahyaluronidase alfa Sub-cutaneous Formulation

Version 5.1	Revision Date: 15.10.2025	SDS Number: 7723970-00018	Date of last issue: 14.04.2025 Date of first issue: 06.01.2021
----------------	------------------------------	------------------------------	---

Materials to avoid	Store locked up. Keep tightly closed. Store in accordance with the particular national regulations. : Do not store with the following product types: Strong oxidizing agents
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Section 8: Exposure controls/personal protection**Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Pembrolizumab	1374853-91-4	TWA	450 µg/m ³ (OEB 2)	Internal
Sucrose	57-50-1	PEL (long term)	10 mg/m ³	SG OEL
		TWA	10 mg/m ³	ACGIH
Berahyaluronidase alfa	2636716-20-4	TLV-C	0.06 ug/m ³ (OEB 5)	Internal
		Further information: RSEN		
		Wipe limit	0.07 ug/100 cm ²	

**Appropriate engineering
control measures**

: The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

No open handling permitted.

Totally enclosed processes and materials transport systems are required.

Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

Pembrolizumab / Berahyaluronidase alfa Sub-cutaneous FormulationVersion
5.1Revision Date:
15.10.2025SDS Number:
7723970-00018Date of last issue: 14.04.2025
Date of first issue: 06.01.2021**Individual protection measures, such as personal protective equipment (PPE)**

Eye/face 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 protection	: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Respiratory protection	: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	: Particulates type
Hand protection	
Material	: Chemical-resistant gloves
Remarks	: Consider double gloving.

Section 9: Physical and chemical properties

Appearance	: liquid
Colour	: No data available
Odour	: No data available
Odour Threshold	: No data available
pH	: 5.5 No data available
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flash point	: No data available
Evaporation rate	: No data available
Flammability (solid, gas)	: Not applicable
Flammability (liquids)	: No data available
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower	: No data available

SAFETY DATA SHEET



Pembrolizumab / Berahyaluronidase alfa Sub-cutaneous Formulation

Version
5.1

Revision Date:
15.10.2025

SDS Number:
7723970-00018

Date of last issue: 14.04.2025
Date of first issue: 06.01.2021

flammability limit

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics

Particle size : Not applicable

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 : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

Section 11: Toxicological information

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

SAFETY DATA SHEET



Pembrolizumab / Berahyaluronidase alfa Sub-cutaneous Formulation

Version
5.1

Revision Date:
15.10.2025

SDS Number:
7723970-00018

Date of last issue: 14.04.2025
Date of first issue: 06.01.2021

Components:

Sucrose:

Acute oral toxicity : LD50 (Rat): 29,700 mg/kg

Berahyaluronidase alfa:

Acute oral toxicity : Remarks: Not classified due to lack of data.

Acute inhalation toxicity : Remarks: Not classified due to lack of data.

Acute dermal toxicity : Remarks: Not classified due to lack of data.

Skin corrosion/irritation

Not classified based on available information.

Components:

Berahyaluronidase alfa:

Remarks : Not classified due to lack of data.

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Berahyaluronidase alfa:

Remarks : Not classified due to lack of data.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Berahyaluronidase alfa:

Result : Sensitiser

Germ cell mutagenicity

Not classified based on available information.

Components:

Sucrose:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative

Berahyaluronidase alfa:

Pembrolizumab / Berahyaluronidase alfa Sub-cutaneous Formulation

Version 5.1 Revision Date: 15.10.2025 SDS Number: 7723970-00018 Date of last issue: 14.04.2025
Date of first issue: 06.01.2021

Genotoxicity in vitro : Remarks: Not classified due to lack of data.

Genotoxicity in vivo : Remarks: Not classified due to lack of data.

Germ cell mutagenicity - Assessment : May cause genetic defects.

Carcinogenicity

Not classified based on available information.

Components:**Berahyaluronidase alfa:**

Remarks : Not classified due to lack of data.

Reproductive toxicity

May damage the unborn child.

Components:**Pembrolizumab:**

Reproductive toxicity - Assessment : May damage the unborn child., Based on data from similar materials

Berahyaluronidase alfa:

Effects on fertility : Remarks: Not classified due to lack of data.
May cause adverse reproductive effects.

Effects on foetal development : Remarks: Not classified due to lack of data.
May cause birth defects.

Reproductive toxicity - Assessment : May damage fertility. May damage the unborn child.

STOT - single exposure

Not classified based on available information.

Components:**Berahyaluronidase alfa:**

Assessment : May cause damage to organs.
Remarks : Not classified due to lack of data.

STOT - repeated exposure

Causes damage to organs (Immune system) through prolonged or repeated exposure if swallowed.

Components:**Pembrolizumab:**

Target Organs : Immune system
Assessment : Causes damage to organs through prolonged or repeated exposure.

Pembrolizumab / Berahyaluronidase alfa Sub-cutaneous FormulationVersion
5.1Revision Date:
15.10.2025SDS Number:
7723970-00018Date of last issue: 14.04.2025
Date of first issue: 06.01.2021**Berahyaluronidase alfa:**

Assessment : May cause damage to organs through prolonged or repeated exposure.
Remarks : Not classified due to lack of data.

Repeated dose toxicity**Components:****Pembrolizumab:**

Species : Monkey
NOAEL : 200 mg/kg
Application Route : Intravenous
Exposure time : 180 d
Remarks : No significant adverse effects were reported

Species : Dog
NOAEL : 200 mg/kg
Application Route : Intravenous
Exposure time : 180 d
Remarks : No significant adverse effects were reported

Berahyaluronidase alfa:

Remarks : Not classified due to lack of data.
May cause damage to organs.

Aspiration toxicity

Not classified based on available information.

Components:**Berahyaluronidase alfa:**

Not applicable

Experience with human exposure**Components:****Pembrolizumab:**

Inhalation : Target Organs: Immune system
Symptoms: Cough, Fatigue, Nausea, pruritis, Rash, constipation, joint pain, Diarrhoea, Pneumonia, decrease in appetite, Fever, anemia, neutropenia, musculoskeletal pain, Vomiting, confusion, Headache, Shortness of breath, Hypofunction of thyroid gland, May cause respiratory arrest., May cause, immune-mediated pneumonitis, colitis, hepatitis, nephritis
Remarks: Damage to fetus possible

Berahyaluronidase alfa:

General Information : Avoid repeated exposure.

SAFETY DATA SHEET



Pembrolizumab / Berahyaluronidase alfa Sub-cutaneous Formulation

Version
5.1

Revision Date:
15.10.2025

SDS Number:
7723970-00018

Date of last issue: 14.04.2025
Date of first issue: 06.01.2021

May cause eye, skin, and respiratory tract irritation.
May be harmful if swallowed.
May be harmful if inhaled.
May produce an allergic reaction.
May cause heritable genetic damage.
May cause adverse reproductive effects.
May cause birth defects.
May cause damage to organs.

Further information

Components:

Berahyaluronidase alfa:

Remarks : The toxicological properties of this material have not been fully investigated

Section 12: Ecological information

Toxicity

Components:

Berahyaluronidase alfa:

Toxicity to fish : Remarks: No data available
Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available
Toxicity to algae/aquatic plants : Remarks: No data available
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available

Ecotoxicology Assessment

Acute aquatic toxicity : No data available
Chronic aquatic toxicity : No data available

Persistence and degradability

Components:

Berahyaluronidase alfa:

Biodegradability : Remarks: No data available
Stability in water : Remarks: No data available

Pembrolizumab / Berahyaluronidase alfa Sub-cutaneous FormulationVersion
5.1Revision Date:
15.10.2025SDS Number:
7723970-00018Date of last issue: 14.04.2025
Date of first issue: 06.01.2021**Bioaccumulative potential****Components:****Sucrose:**

Partition coefficient: n-octanol/water : Pow: < 1

Mobility in soil

No data available

Other adverse effects

No data available

Section 13: Disposal considerations**Disposal methods**

Waste from residues	: Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
Contaminated packaging	: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

Section 14: Transport information**International Regulations****UNRTDG**

Not regulated as a dangerous good

UN number	: Not applicable
UN proper shipping name	: Not applicable
Transport hazard class(es)	: Not applicable
Subsidiary risk	: Not applicable
Packing group	: Not applicable
Labels	: Not applicable
Environmentally hazardous	: no

IATA-DGR

Not regulated as a dangerous good

UN/ID No.	: Not applicable
UN proper shipping name	: Not applicable
Transport hazard class(es)	: Not applicable
Subsidiary risk	: Not applicable
Packing group	: Not applicable
Labels	: Not applicable
Packing instruction (cargo aircraft)	: Not applicable
Packing instruction (passenger aircraft)	: Not applicable

IMDG-Code

Not regulated as a dangerous good

UN number	: Not applicable
UN proper shipping name	: Not applicable

SAFETY DATA SHEET



Pembrolizumab / Berahyaluronidase alfa Sub-cutaneous Formulation

Version 5.1 Revision Date: 15.10.2025 SDS Number: 7723970-00018 Date of last issue: 14.04.2025
Date of first issue: 06.01.2021

Transport hazard class(es) : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

Section 15: Regulatory information

Safety, health and environmental regulations specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subject to the requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable

Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable
Regulations

The components of this product are reported in the following inventories:

CA. DSL : not determined

AICS : not determined

IECSC : not determined

Section 16: Other information

Revision Date : 15.10.2025

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

SG OEL : Singapore. Workplace Safety and Health (General Provisions) Regulations - First Schedule Permissible Exposure Limits of Toxic Substances.

ACGIH / TWA : 8-hour, time-weighted average

SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

SAFETY DATA SHEET



Pembrolizumab / Berahyaluronidase alfa Sub-cutaneous Formulation

Version
5.1

Revision Date:
15.10.2025

SDS Number:
7723970-00018

Date of last issue: 14.04.2025
Date of first issue: 06.01.2021

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 Standardisation; 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 Harmonised 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 Organisation; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; 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 Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organisation 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, Authorisation 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

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

SG / EN