

# SAFETY DATA SHEET



## Pembrolizumab Liquid Formulation

Version 5.0      Revision Date: 06.04.2024      SDS Number: 49580-00026      Date of last issue: 30.09.2023  
Date of first issue: 23.01.2015

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### Section 1: Identification

**Product identifier** : Pembrolizumab Liquid Formulation

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

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

**Manufacturer or supplier's details**

Company : MSD  
Address : 50 Tuas West Drive  
Singapore - Singapore 638408  
Telephone : +1-908-740-4000  
Emergency telephone number : 65 6697 2111 (24/7/365)  
E-mail address : EHSDATASTEWARD@msd.com

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### Section 2: Hazard identification

**Classification of the substance or mixture**

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Immune system)

**GHS Label elements, including precautionary statements**

Hazard pictograms	:
Signal word	: Danger
Hazard statements	: H360D May damage the unborn child. H373 May cause damage to organs (Immune system) through prolonged or repeated exposure if swallowed.
Precautionary statements	: <b>Prevention:</b> 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. P280 Wear protective gloves/ protective clothing/ eye protec-

# SAFETY DATA SHEET



## Pembrolizumab Liquid Formulation

---

Version 5.0	Revision Date: 06.04.2024	SDS Number: 49580-00026	Date of last issue: 30.09.2023 Date of first issue: 23.01.2015
----------------	------------------------------	----------------------------	---

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tion/ 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.

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### Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

**Components**

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

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### 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.

**Most important symptoms and effects, both acute and delayed**

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

Protection of first-aiders : First Aid responders should pay attention to self-protection,

# SAFETY DATA SHEET



## Pembrolizumab Liquid Formulation

Version 5.0      Revision Date: 06.04.2024      SDS Number: 49580-00026      Date of last issue: 30.09.2023  
Date of first issue: 23.01.2015

---

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.

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## Section 5: Fire-fighting measures

### Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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  
Nitrogen oxides (NO<sub>x</sub>)

### 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.

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## 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.  
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

# SAFETY DATA SHEET



## Pembrolizumab Liquid Formulation

Version  
5.0

Revision Date:  
06.04.2024

SDS Number:  
49580-00026

Date of last issue: 30.09.2023  
Date of first issue: 23.01.2015

---

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.

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### 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.

#### Conditions for safe storage, including any incompatibilities

Conditions for safe storage	: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Materials to avoid	: 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

# SAFETY DATA SHEET



## Pembrolizumab Liquid Formulation

Version 5.0	Revision Date: 06.04.2024	SDS Number: 49580-00026	Date of last issue: 30.09.2023 Date of first issue: 23.01.2015
----------------	------------------------------	----------------------------	---

Components	CAS-No.	Value type (Form of exposure)	Control param- eters / Permissible concentration	Basis
Sucrose	57-50-1	PEL (long term)	10 mg/m <sup>3</sup>	SG OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Pembrolizumab	1374853-91- 4	TWA	450 µg/m <sup>3</sup> (OEB 2)	Internal

**Appropriate engineering control measures** : Minimize workplace exposure concentrations. If sufficient ventilation is unavailable, use with local exhaust ventilation.

### Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection : Wear the following personal protective equipment:  
Safety glasses

Skin protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.  
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

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 : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

### Section 9: Physical and chemical properties

Appearance : suspension

Colour : Colorless to pale yellow

Odour : No data available

Odour Threshold : No data available

pH : 5.5

Melting point/freezing point : No data available

# SAFETY DATA SHEET



## Pembrolizumab Liquid Formulation

Version 5.0      Revision Date: 06.04.2024      SDS Number: 49580-00026      Date of last issue: 30.09.2023  
Date of first issue: 23.01.2015

---

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 flammability limit	: No data available
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	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, dynamic	: No data available
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	: No data available

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## Section 10: Stability and reactivity

# SAFETY DATA SHEET



## Pembrolizumab Liquid Formulation

Version 5.0      Revision Date: 06.04.2024      SDS Number: 49580-00026      Date of last issue: 30.09.2023  
Date of first issue: 23.01.2015

---

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.

#### Components:

##### **Sucrose:**

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

##### **Skin corrosion/irritation**

Not classified based on available information.

##### **Serious eye damage/eye irritation**

Not classified based on available information.

##### **Respiratory or skin sensitisation**

##### **Skin sensitisation**

Not classified based on available information.

##### **Respiratory sensitisation**

Not classified based on available information.

##### **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

##### **Carcinogenicity**

Not classified based on available information.

##### **Reproductive toxicity**

May damage the unborn child.

# SAFETY DATA SHEET



## Pembrolizumab Liquid Formulation

Version  
5.0

Revision Date:  
06.04.2024

SDS Number:  
49580-00026

Date of last issue: 30.09.2023  
Date of first issue: 23.01.2015

---

### Components:

#### **Pembrolizumab:**

Reproductive toxicity - Assessment	: May damage the unborn child., Based on data from similar materials
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#### **STOT - single exposure**

Not classified based on available information.

#### **STOT - repeated exposure**

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

### Components:

#### **Pembrolizumab:**

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

#### **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

#### **Aspiration toxicity**

Not classified based on available information.

#### **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
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## SAFETY DATA SHEET



## Pembrolizumab Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023  
5.0 06.04.2024 49580-00026 Date of first issue: 23.01.2015

1

Remarks: Damage to fetus possible

## Section 12: Ecological information

## Toxicity

No data available

## Persistence and degradability

No data available

### Bioaccumulative potential

## Components:

## Sucrose-

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

## Mobility in soil

## Mobility in 6G

## Other adverse effects

### Other adverse effects

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## Section 13: Disposal considerations

## Disposal methods

<b>Disposal methods</b>	
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.

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## Section 14: Transport information

## International Regulations

UNRTDG

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

<b>IATA-DGR</b>		
UN/ID No.	:	Not applicable
UN proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable

# SAFETY DATA SHEET



## Pembrolizumab Liquid Formulation

Version 5.0      Revision Date: 06.04.2024      SDS Number: 49580-00026      Date of last issue: 30.09.2023  
Date of first issue: 23.01.2015

---

Packing instruction (cargo aircraft) : Not applicable

Packing instruction (passenger aircraft) : Not applicable

### IMDG-Code

UN number : Not applicable

UN proper shipping name : Not applicable

Class : 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

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## 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 subjected to the SDS, labelling, PEL and other 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:

AICS : not determined

DSL : not determined

IECSC : not determined

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## Section 16: Other information

Revision Date : 06.04.2024

### Further information

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

**Pembrolizumab Liquid Formulation**

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Version 5.0	Revision Date: 06.04.2024	SDS Number: 49580-00026	Date of last issue: 30.09.2023 Date of first issue: 23.01.2015
----------------	------------------------------	----------------------------	---

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Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : dd.mm.yyy

**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

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 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 Organisation for Standardization; KECL - 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; 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 - 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, 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

# SAFETY DATA SHEET



## Pembrolizumab Liquid Formulation

---

Version 5.0	Revision Date: 06.04.2024	SDS Number: 49580-00026	Date of last issue: 30.09.2023 Date of first issue: 23.01.2015
----------------	------------------------------	----------------------------	---

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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