

## Pembrolizumab Liquid Formulation

Version 5.9      Revision Date: 30.09.2023      SDS Number: 49549-00025      Date of last issue: 04.04.2023  
Date of first issue: 23.01.2015

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### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Pembrolizumab Liquid Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530  
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification in accordance with ABNT NBR 14725 Standard

Reproductive toxicity : Category 1B

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

#### GHS label elements in accordance with ABNT NBR 14725 Standard

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 : **Prevention:**  
P201 Obtain special instructions before use.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  
**Response:**  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

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### Storage:

P405 Store locked up.

### Other hazards which do not result in classification

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Sucrose	57-50-1		>= 5 -< 10
Pembrolizumab	1374853-91-4	Reproductive toxicity, Category 1B Specific target organ toxicity - repeated exposure (Oral) (Immune system), Category 1	>= 1 -< 5

## SECTION 4. 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 : 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, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

## SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray

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		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 Nitrogen oxides (NO <sub>x</sub> )
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.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. 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 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	:	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. 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

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.

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- Do not breathe mist or vapors.  
 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.
- Conditions for safe storage** : Wash contaminated clothing before re-use.  
 Keep in properly labeled containers.  
 Store locked up.  
 Keep tightly closed.
- Materials to avoid** : Store in accordance with the particular national regulations.  
 Do not store with the following product types:  
 Strong oxidizing agents  
 Self-reactive substances and mixtures  
 Organic peroxides  
 Explosives  
 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
Sucrose	57-50-1	TWA	10 mg/m <sup>3</sup>	ACGIH
Pembrolizumab	1374853-91-4	TWA	450 µg/m <sup>3</sup> (OEB 2)	Internal

- Engineering measures** : Minimize workplace exposure concentrations.  
 If sufficient ventilation is unavailable, use with local exhaust ventilation.

#### Personal protective equipment

- 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 specific to place of work. Breakthrough time is not determined for the product. Change gloves often!

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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.

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

Skin and body 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).

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	suspension
Color	:	Colorless to pale yellow
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	5,5
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 flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-	:	No data available

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octanol/water  
Autoignition 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 size : No data available

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**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.

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**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.



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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, Diarrhea, 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
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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity**

No data available

**Persistence and degradability**

No data available

**Bioaccumulative potential****Components:****Sucrose:**

Partition coefficient: n-octanol/water	:	Pow: < 1
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**Mobility in soil**

No data available

**Other adverse effects**

No data available

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**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.



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**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 for product as supplied.

**Domestic regulation****ANTT**

Not regulated as a dangerous good

**Special precautions for user**

Not applicable

**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

**SECTION 16. OTHER INFORMATION**Revision Date : 30.09.2023  
Date format : dd.mm.yyyy**Further information**Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>**Full text of other abbreviations**

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ACGIH : USA. ACGIH Threshold Limit Values (TLV)

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

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; 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; 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; TECl - 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.

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