

**Pembrolizumab Solid Formulation**

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 06.04.2024  |
| 4.1     | 14.04.2025     | 525401-00020 | Date of first issue: 23.02.2016 |

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**Section 1: Identification**

**Product identifier** : Pembrolizumab Solid 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 1 (Immune system)

**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 dust.  
P264 Wash skin thoroughly after handling.

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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**

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

**Section 3: Composition/information on ingredients**

Substance / Mixture : Mixture

**Components**

| Chemical name | CAS-No.      | Concentration (% w/w) |
|---------------|--------------|-----------------------|
| Sucrose       | 57-50-1      | >= 70 -< 90           |
| Pembrolizumab | 1374853-91-4 | >= 20 -< 30           |

**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 : If in eyes, rinse well with water.  
Get medical attention if irritation develops and persists.

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

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

|                            |   |   |
|----------------------------|---|---|
| Risks                      | : | Contact with dust can cause mechanical irritation or drying of the skin.<br>Dust contact with the eyes can lead to mechanical irritation.<br>May damage the unborn child.<br>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. |
|-----------|---|---|

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**Section 5: Fire-fighting measures****Extinguishing media**

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

|                                |   |             |
|--------------------------------|---|-------------|
| Unsuitable extinguishing media | : | None known. |
|--------------------------------|---|-------------|

**Special hazards arising from the substance or mixture**

|                                       |   |   |
|---------------------------------------|---|---|
| Specific hazards during fire-fighting | : | Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.<br>Exposure to combustion products may be a hazard to health. |
|---------------------------------------|---|---|

|                               |   |   |
|-------------------------------|---|---|
| Hazardous combustion products | : | Carbon oxides<br>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.<br>Use personal protective equipment. |
|---|---|--|

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

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**Section 6: Accidental release measures****Personal precautions, protective equipment and emergency procedures**

|                      |   |                                    |
|----------------------|---|------------------------------------|
| Personal precautions | : | Use personal protective equipment. |
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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.  
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 : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
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 : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

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 dust.  
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.  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
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

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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

**Section 8: Exposure controls/personal protection****Control parameters****Occupational Exposure Limits**

| Components    | CAS-No.      | Value type<br>(Form of exposure) | Control parameters / 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.  
Apply measures to prevent dust explosions.  
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).  
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 goggles

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

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|          |   |
|----------|---|
| 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                                       | : powder  |
| Colour   | : white to off-white  |
| Odour  | : No data available   |
| Odour Threshold                                  | : No data available   |
| pH   | : No data available   |
| Melting point/freezing point                     | : No data available   |
| Initial boiling point and boiling range          | : No data available   |
| Flash point                                      | : Not applicable  |
| Evaporation rate                                 | : No data available   |
| Flammability (solid, gas)                        | : May form explosive dust-air mixture during processing, handling or other means. |
| 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)<br>Water solubility              | : No data available   |

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|  |   |  |
|--|---|--|
| 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**

|                                    |   |  |
|------------------------------------|---|--|
| Reactivity                         | : | Not classified as a reactivity hazard.   |
| Chemical stability                 | : | Stable under normal conditions.  |
| Possibility of hazardous reactions | : | May form explosive dust-air mixture during processing, handling or other means.<br>Can react with strong oxidizing agents. |
| Conditions to avoid                | : | Heat, flames and sparks.<br>Avoid dust formation.  |
| 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<br>Skin contact<br>Ingestion<br>Eye contact |
|--|---|--|

**Acute toxicity**

Not classified based on available information.

**Components:****Sucrose:**

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

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**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.

**Components:****Pembrolizumab:**

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

**STOT - single exposure**

Not classified based on available information.

**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.



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**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<br>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<br>Remarks: Damage to fetus possible |
|------------|---|--|

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**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**

No data available

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**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.<br>Dispose of in accordance with local regulations.   |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>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**

|  |   |                |
|--|---|----------------|
| 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**

|                            |   |                |
|----------------------------|---|----------------|
| 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 |
| 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 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:**

AICS : not determined

DSL : not determined

IECSC : not determined

**Section 16: Other information**

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**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

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

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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; 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.

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