according to GB/T 16483 and GB/T 17519



# **Pembrolizumab Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 5.0 2024/09/28 525380-00019 Date of first issue: 2016/02/23

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Pembrolizumab Solid Formulation

Manufacturer or supplier's details

Company : MSD

Address : 199 Wenhai North Road

HEDA, Hangzhou - Zhejiang Province - CHINA 310018

Telephone : 908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

#### 2. HAZARDS IDENTIFICATION

## **Emergency Overview**

**Appearance** : powder

Colour: white to off-whiteOdour: No data available

May damage the unborn child. Causes damage to organs through prolonged or repeated expo-

sure.

**GHS Classification** 

Reproductive toxicity : Category 1B

Specific target organ toxicity - :

repeated exposure

Category 1

**GHS** label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : H360D May damage the unborn child.

H372 Causes damage to organs through prolonged or repeated

according to GB/T 16483 and GB/T 17519



# **Pembrolizumab Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 5.0 2024/09/28 525380-00019 Date of first issue: 2016/02/23

exposure.

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.

P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face 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.

## Physical and chemical hazards

Not classified based on available information.

#### **Health hazards**

May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

## **Environmental hazards**

Not classified based on available information.

## 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.

#### 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	

## 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

according to GB/T 16483 and GB/T 17519



## Pembrolizumab Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 5.0 2024/09/28 525380-00019 Date of first issue: 2016/02/23

vice 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.

If in eyes, rinse well with water. In case of eye contact

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.

Causes damage to organs through prolonged or repeated

exposure.

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation. 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).

Treat symptomatically and supportively. Notes to physician

# 5. FIREFIGHTING MEASURES

Protection of first-aiders

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

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.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

Carbon oxides

Nitrogen oxides (NOx)

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

according to GB/T 16483 and GB/T 17519



# Pembrolizumab Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 525380-00019 5.0 2024/09/28 Date of first issue: 2016/02/23

for firefighters

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

Use personal protective equipment.

#### **6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec: :

tive equipment and emergency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

**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 Sweep up or vacuum up spillage and collect in suitable con-

tainer 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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

## 7. HANDLING AND STORAGE

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 as-

sessment

Keep container tightly closed.

Minimize dust generation and accumulation.

according to GB/T 16483 and GB/T 17519



# **Pembrolizumab Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 5.0 2024/09/28 525380-00019 Date of first issue: 2016/02/23

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.

Avoidance of contact : Oxidizing agents

Storage

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

Packaging material : Unsuitable material: None known.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

# Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
		exposure)	Concentiation	
Sucrose	57-50-1	TWA	10 mg/m3	ACGIH
Pembrolizumab	1374853-91- 4	TWA	450 μg/m3 (OEB 2)	Internal

**Engineering 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.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type : Particulates type

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

Safety goggles

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).

Hand protection

according to GB/T 16483 and GB/T 17519



# **Pembrolizumab Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 5.0 2024/09/28 525380-00019 Date of first issue: 2016/02/23

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.

Hygiene measures : If exposure to chemical is likely during typical use, provide

eye flushing systems and safety showers close to the work-

ing place.

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

#### 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, han-

dling 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

according to GB/T 16483 and GB/T 17519



# **Pembrolizumab Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 5.0 2024/09/28 525380-00019 Date of first issue: 2016/02/23

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

#### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

products

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Hazardous decomposition

: Oxidizing agents

No hazardous decomposition products are known.

#### 11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation

Skin contact Ingestion Eye contact

according to GB/T 16483 and GB/T 17519



# **Pembrolizumab Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 5.0 2024/09/28 525380-00019 Date of first issue: 2016/02/23

## **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.

# **Components:**

# Pembrolizumab:

Reproductive toxicity - As-

sessment

: 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 through prolonged or repeated exposure.

according to GB/T 16483 and GB/T 17519



# **Pembrolizumab Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 5.0 2024/09/28 525380-00019 Date of first issue: 2016/02/23

#### **Components:**

#### Pembrolizumab:

Target Organs : Immune system

Assessment : 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

Remarks: Damage to fetus possible

## 12. ECOLOGICAL INFORMATION

## **Ecotoxicity**

No data available

## Persistence and degradability

No data available

according to GB/T 16483 and GB/T 17519



# **Pembrolizumab Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 5.0 2024/09/28 525380-00019 Date of first issue: 2016/02/23

#### Bioaccumulative potential

## **Components:**

Sucrose:

Partition coefficient: n-

octanol/water

: Pow: < 1

Mobility in soil

No data available

Other adverse effects

No data available

#### 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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

## 14. TRANSPORT INFORMATION

## **International Regulations**

**UNRTDG** 

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo : Not applicable

aircraft)

Packing instruction (passen-

racking instruction (pa

ger aircraft)

Not applicable

**IMDG-Code** 

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable

according to GB/T 16483 and GB/T 17519



# **Pembrolizumab Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 5.0 2024/09/28 525380-00019 Date of first issue: 2016/02/23

Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable

Marine pollutant : no

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

Not applicable for product as supplied.

## **National Regulations**

GB 6944/12268

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Marine pollutant : no

Special precautions for user

Not applicable

#### 15. REGULATORY INFORMATION

## National regulatory information

Law on the Prevention and Control of Occupational Diseases

#### **Regulations on Safety Management of Hazardous Chemicals**

Catalogue of Hazardous Chemicals : This product is not listed in the cata-

logue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of de-

termination.

Identification of Major Hazard Installations for Hazardous Chemicals (GB : Not listed

18218)

Hazardous Chemicals for Priority Management under : Not listed

SAWS

## Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals : Not listed

# Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import : Not listed

and Export

#### Regulation on the Administration of Precursor Chemicals

according to GB/T 16483 and GB/T 17519



## Pembrolizumab Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 5.0 2024/09/28 525380-00019 Date of first issue: 2016/02/23

Catalogue and Classification of Precursor Chemicals : Not listed

## **Yangtze River Protection Law**

This product does not contain any dangerous chemicals prohibited for inland river transport.

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

**AICS** not determined

DSL not determined

**IECSC** not determined

#### **16. OTHER INFORMATION**

**Revision Date** 2024/09/28

**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 Agen-

cy, http://echa.europa.eu/

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

Date format : yyyy/mm/dd

Full text of other abbreviations

**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

according to GB/T 16483 and GB/T 17519



## **Pembrolizumab Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 5.0 2024/09/28 525380-00019 Date of first issue: 2016/02/23

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

#### **Disclaimer**

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.

CN / EN