According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pembrolizumab Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 28.09.2024

 3.6
 14.04.2025
 9371562-00011
 Date of first issue: 27.08.2021

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Pembrolizumab Liquid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-

stance/Mixture

: Pharmaceutical

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

120 Moorgate

EC2M 6UR London, United Kingdom

Telephone : +44 (0) 2081548000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Reproductive toxicity, Category 1B H360D: May damage the unborn child.

Specific target organ toxicity - repeated

exposure, Category 2

H373: May cause damage to organs through pro-

longed or repeated exposure.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pembrolizumab Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 28.09.2024

 3.6
 14.04.2025
 9371562-00011
 Date of first issue: 27.08.2021

Hazard pictograms :

Signal word : Danger

Hazard statements : H360D May damage the unborn child.

H373 May cause damage to organs through prolonged

or repeated exposure.

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.

Storage:

P405 Store locked up.

Hazardous components which must be listed on the label:

Pembrolizumab

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Pembrolizumab	1374853-91-4	Repr. 1B; H360D STOT RE 1; H372 (Immune system)	>= 1 - < 10
Substances with a workplace exposure	e limit :		
Sucrose	57-50-1 200-334-9		>= 1 - < 10

For explanation of abbreviations see section 16.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pembrolizumab Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 28.09.2024 3.6 14.04.2025 9371562-00011 Date of first issue: 27.08.2021

SECTION 4: First aid measures

4.1 Description of first aid measures

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

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

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).

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.

4.2 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.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pembrolizumab Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 28.09.2024

 3.6
 14.04.2025
 9371562-00011
 Date of first issue: 27.08.2021

5.2 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 prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx)

5.3 Advice for firefighters

Special protective equipment :

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

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

tective equipment recommendations (see section 8).

6.2 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.

If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

6.3 Methods and material 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 absor-

bent.

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.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pembrolizumab Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 28.09.2024

 3.6
 14.04.2025
 9371562-00011
 Date of first issue: 27.08.2021

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 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 as-

sessment

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 contami-

nated clothing before re-use.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage

areas and containers

Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national

equiptions

regulations.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sucrose	57-50-1	TWA	10 mg/m3	GB EH40

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pembrolizumab Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 28.09.2024

 3.6
 14.04.2025
 9371562-00011
 Date of first issue: 27.08.2021

		STEL	20 mg/m3	GB EH40
Pembrolizumab	1374853- 91-4	TWA	450 μg/m3 (OEB 2)	Internal

Derived No Effect Level (DNEL)

Substance name	End Use	Exposure routes	Potential health effects	Value
Histidine	Workers	Inhalation	Long-term systemic effects	83.38 mg/m3
	Workers	Skin contact	Long-term systemic effects	236.45 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	20.56 mg/m3
	Consumers	Skin contact	Long-term systemic effects	118.2 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	11.8 mg/kg bw/day

Predicted No Effect Concentration (PNEC)

Substance name	Environmental Compartment	Value
Histidine	Fresh water	0.1 mg/l
	Freshwater - intermittent	1 mg/l
	Marine water	0.01 mg/l
	Marine water - intermittent	1 mg/l
	Sewage treatment plant	20.5 mg/l
	Fresh water sediment	0.392 mg/kg dry weight (d.w.)
	Marine sediment	0.039 mg/kg dry weight (d.w.)
	Soil	0.02 mg/kg dry weight (d.w.)

8.2 Exposure controls

Engineering measures

Minimize workplace exposure concentrations.

If sufficient ventilation is unavailable, use with local exhaust ventilation.

Personal protective equipment

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

Safety glasses

Equipment should conform to BS EN 166

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

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pembrolizumab Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 28.09.2024 3.6 14.04.2025 9371562-00011 Date of first issue: 27.08.2021

glove manufacturer. Wash hands before breaks and at the

end of workday.

Skin and body protection : Select appropriate protective clothing based on chemical re-

sistance data and an assessment of the local exposure poten-

tial.

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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Equipment should conform to BS EN 143

Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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

Initial boiling point and boiling

range

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

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- : No data available

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pembrolizumab Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 28.09.2024 3.6 14.04.2025 9371562-00011 Date of first issue: 27.08.2021

octanol/water

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.

9.2 Other information

Molecular weight : No data available

Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of : Inhalation

exposure Skin contact

Ingestion Eye contact

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pembrolizumab Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 28.09.2024

 3.6
 14.04.2025
 9371562-00011
 Date of first issue: 27.08.2021

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- : Ma

May damage the unborn child., Based on data from similar

sessment materials

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Pembrolizumab:

Target Organs : Immune system

Assessment : Causes damage to organs through prolonged or repeated

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pembrolizumab Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 28.09.2024 3.6 14.04.2025 9371562-00011 Date of first issue: 27.08.2021

exposure.

Repeated dose toxicity

Components:

Pembrolizumab:

Species Monkey 200 mg/kg NOAEL 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

SECTION 12: Ecological information

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

Components:

Sucrose:

Partition coefficient: n- : Pow: < 1

octanol/water

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pembrolizumab Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 28.09.2024 14.04.2025 9371562-00011 Date of first issue: 27.08.2021 3.6

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment This substance/mixture contains no components considered

> to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

12.6 Other adverse effects

Product:

Endocrine disrupting poten-

tial

This substance/mixture does not contain components considered to have endocrine disrupting properties for environment

according to UK REACH Article 57(f).

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

Empty containers should be taken to an approved waste han-Contaminated packaging

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADN Not regulated as a dangerous good **ADR** Not regulated as a dangerous good RID Not regulated as a dangerous good **IMDG** Not regulated as a dangerous good **IATA** Not regulated as a dangerous good

14.2 UN proper shipping name

ADN Not regulated as a dangerous good **ADR** Not regulated as a dangerous good RID Not regulated as a dangerous good **IMDG** Not regulated as a dangerous good

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pembrolizumab Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 28.09.2024 3.6 14.04.2025 9371562-00011 Date of first issue: 27.08.2021

IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADR : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.4 Packing group

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA (Cargo) : Not regulated as a dangerous good
IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Conditions of restriction for the fol-

lowing entries should be considered:

Number on list 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or

not.

UK REACH Candidate list of substances of very high

concern (SVHC) for Authorisation

Not applicable

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pembrolizumab Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 28.09.2024

 3.6
 14.04.2025
 9371562-00011
 Date of first issue: 27.08.2021

The Persistent Organic Pollutants Regulations (retained : Not applicable

Regulation (EU) 2019/1021 as amended for Great Brit-

ain)

Regulation (EU) No 2024/590 on substances that de- : Not applicable

plete the ozone layer

UK REACH List of substances subject to authorisation : Not applicable

(Annex XIV)

GB Export and import of hazardous chemicals - Prior : Not applicable

Informed Consent (PIC) Regulation

Control of Major Accident Hazards Regulations 2015 (COMAH)

Not applicable

Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

Full text of H-Statements

H360D : May damage the unborn child.

H372 : Causes damage to organs through prolonged or repeated

exposure if swallowed.

Full text of other abbreviations

Repr. : Reproductive toxicity

STOT RE : Specific target organ toxicity - repeated exposure GB EH40 : UK. EH40 WEL - Workplace Exposure Limits

GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL : Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regula-

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pembrolizumab Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 28.09.2024

 3.6
 14.04.2025
 9371562-00011
 Date of first issue: 27.08.2021

tion (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

Further information

Sources of key data used to : compile the Safety Data

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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

Classification of the mixture: Classification procedure:

Repr. 1B H360D Calculation method STOT RE 2 H373 Calculation method

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.

GB / EN

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pembrolizumab Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 28.09.2024

 3.6
 14.04.2025
 9371562-00011
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