# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878

# Pembrolizumab Liquid Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
|---|---|---|---|
| 4.13 | 28.09.2024 | 51411-00028 | Date of first issue: 23.01.2015 |

## 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 Substance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

### 1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

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)**

| | |
|---|---|
| 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 prolonged or repeated exposure. |

### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008)**

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.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

**Components**

| Chemical name | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification | Concentration (% w/w) |
|---|---|---|---|
| Pembrolizumab | 1374853-91-4 | Repr. 1B; H360D<br>STOT RE 1; H372 (Immune system) | >= 1 - < 10 |

For explanation of abbreviations see section 16.

## 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 advice 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.

### 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 products : 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.<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. |

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

| | | |
|---|---|---|
| Personal precautions | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |

### 6.2 Environmental precautions

| | | |
|---|---|---|
| Environmental precautions | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g. by containment or oil barriers).<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained. |

### 6.3 Methods and material for containment and cleaning up

| | | |
|---|---|---|
| Methods for cleaning up | : | Soak up with inert absorbent material.<br>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.<br>Clean up remaining materials from spill with suitable absorbent.<br>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.<br>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

### 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 assessment
Keep container tightly closed.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

### 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 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 |
|---|---|---|---|---|
| Pembrolizumab | 1374853-91-4 | TWA | 450 µg/m3 (OEB 2) | Internal |

**Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006**

| 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) according to Regulation (EC) No. 1907/2006**

| 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 NS 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 glove manufacturer. Wash hands before breaks and at the end of workday.

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).

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

| | | |
|---|---|---|
| | | Equipment should conform to NS EN 143 |
| Filter type | : | Particulates type (P) |

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

| | | |
|---|---|---|
| Physical state | : | suspension |
| Colour | : | Colorless to pale yellow |
| Odour | : | No data available |
| Odour Threshold | : | No data available |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | 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 |
| Flash point | : | No data available |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| pH | : | 5,5 |
| Viscosity | | |
| Viscosity, dynamic | : | No data available |
| Viscosity, kinematic | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| Vapour pressure | : | No data available |

| | | |
|---|---|---|
| Relative density | : | No data available |
| Density | : | No data available |
| Relative vapour density | : | No data available |
| Particle characteristics<br>Particle size | : | No data available |

**9.2 Other information**

| | | |
|---|---|---|
| Explosives | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Evaporation rate | : | No data available |
| Molecular weight | : | 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 hazard classes as defined in Regulation (EC) No 1272/2008**

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

**Acute toxicity**

Not classified based on available information.

**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.

**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**

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 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.

### 11.2 Information on other hazards

**Endocrine disrupting properties**

**Product:**

| | | |
|---|---|---|
| Assessment | : | The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher. |

**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 |

## SECTION 12: Ecological information

### 12.1 Toxicity

No data available

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

No data available

### 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 Endocrine disrupting properties

**Product:**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 12.7 Other adverse effects

No data available

## 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.

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.

## SECTION 14: Transport information

### 14.1 UN number or ID 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

**IATA** : Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

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

### 14.4 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 Maritime transport in bulk according to IMO instruments

| | | |
|---|---|---|
| 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

| | | |
|---|---|---|
| REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) | : | Conditions of restriction for the following entries should be considered: Number on list 3<br><br>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. |
| REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). | : | Not applicable |
| REACH - List of substances subject to authorisation (Annex XIV) | : | Not applicable |
| Regulation (EC) on substances that deplete the ozone | : | Not applicable |

layer

| | | |
|---|---|---|
| Regulation (EU) 2019/1021 on persistent organic pollutants (recast) | : | Not applicable |
| Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals | : | Not applicable |

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

**Other regulations:**

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.
Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

**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 |

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; Regulation (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 La-

boratory 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 Sheet | : | Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, 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.

NO / EN