**SAFETY DATA SHEET**

**Pembrolizumab Liquid Formulation**

**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

1.3 **Details of the supplier of the safety data sheet**
   - Company: MSD
     - 117 16th Road
     - 07033 Halfway house, Midrand, South Africa
   - Telephone: +27 11 655 3000
   - Telefax: 908-735-1496
   - 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 protec-
Hazardous components which must be listed on the label:

Pembrolizumab

2.3 Other hazards
None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (%) w/w</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pembrolizumab</td>
<td>1374853-91-4</td>
<td></td>
<td></td>
<td></td>
<td>Repr.1B; H360D STOT RE1; H372</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
</tbody>
</table>

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.
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 firefighting: 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. Use personal protective equipment.

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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.
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6.2 Environmental precautions
Environmental precautions: Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

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 absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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 vapours or spray mist.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
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
- 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**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>TWA OEL-RL</td>
<td>10 mg/m³</td>
<td>ZA OEL</td>
</tr>
<tr>
<td>Pembrolizumab</td>
<td>1374853-91-4</td>
<td>TWA</td>
<td>75 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information</td>
<td>Recommended Limit</td>
<td>STEL OEL-RL</td>
<td>20 mg/m³</td>
<td>ZA OEL</td>
</tr>
</tbody>
</table>

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

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

**Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Histidine</td>
<td>Fresh water</td>
<td>0.1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.01 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water - intermittent</td>
<td>1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>20.5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>0.392 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.039 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.02 mg/kg dry</td>
</tr>
</tbody>
</table>
8.2 Exposure controls

**Engineering measures**

Minimize workplace exposure concentrations.
If sufficient ventilation is unavailable, use with local exhaust ventilation.

**Personal protective equipment**

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

**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.

**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.

**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** : No data available

**Flash point** : No data available

**Evaporation rate** : No data available

**Flammability (solid, gas)** : Not applicable

**Upper explosion limit / Upper flammability limit** : No data available
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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-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.

9.2 Other information
Flammability (liquids) : No data available
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 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 Assessment: Immune system
- Causes damage to organs through prolonged or repeated exposure.
Repeated dose toxicity

Components:

Pembrolizumab:

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>200 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intravenous</td>
</tr>
<tr>
<td>Exposure time</td>
<td>180 d</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

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

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other adverse effects

No data available
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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.

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
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
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

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
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Pembrolizumab Liquid Formulation

Version 4.0
Revision Date: 09/13/2019
SDS Number: 49583-00015
Date of last issue: 24.04.2019
Date of first issue: 23.01.2015

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
ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit
ZA OEL / STEL OEL-RL : Short term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways;
ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road;
AICS - Australian Inventory of Chemical Substances;
ASTM - American Society for the Testing of Materials;
bw - Body weight;
CLP - Classification Labelling Packaging Regulation;
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;
GHST - Globally Harmonized System;
GLP - Good Laboratory Practice;
IARC - International Agency for Research on Cancer;
ICAO - International Civil Aviation Organization;
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 - Japan Industrial Safety and Health Law;
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);
MA RPOL - International Convention for the Prevention of Pollution from Ships;
OECD - Organization for Economic Co-operation and Development;
OPPTS - Office of Chemical Safety and Pollution Prevention;
RID - Regulations concerning the International Carriage of Dangerous Goods by Road;
SADT - Self-Accelerating Decomposition Temperature;
SDS - Safety Data Sheet;
SVHC - Substance of very high concern;
TCSI - Taiwan Chemical Substance Inventory;
UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods;
vPvB - Very Persistent and Very Bioaccumulative

Further information
Classification of the mixture:

<table>
<thead>
<tr>
<th>Repr.</th>
<th>H360D</th>
</tr>
</thead>
<tbody>
<tr>
<td>STOT RE 2</td>
<td>H373</td>
</tr>
</tbody>
</table>

Classification procedure:

Calculation method

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

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.