

SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product name: Pembrolizumab Formulation**SDS No:** 300000000675**Synonyms, Trade Names:**

MK-3475 Lyophilisate

Manufacturer:Merck
One Merck Drive P.O. Box 100
Whitehouse Station, NJ, USA 08889-0100**Telephone:** 908-423-1000 (General Information Only)**Fax:** 908-735-1496**Contact Person:** EHS Data Steward**e-mail:** MSDS@merck.com**Emergency telephone:** 1-908-423-6000
(24/7/365) English Only**Intended Use:** Finished pharmaceutical product: Intended for the treatment of cancer.

2 HAZARDS IDENTIFICATION

Emergency Overview:**Appearance:****Color:** White to off-white
Form : Lyophilized powder**Signal words** Danger**Potential Health Effects:****General** Finished pharmaceutical product. May cause harm to the unborn child. Obtain special instructions before use. Avoid contact with skin and eyes. Wash thoroughly after handling.**Potential Physical / Chemical Effects:**

None expected with normal handling of finished product.

Inhalation:

No data available for finished product. Avoid breathing dust.

skin:

No data available for finished product.

eye:

No data available for finished product. Avoid contact with eyes.

Ingestion:

No data available for finished product.

Signs and Symptoms:

May cause harm to the unborn child.

Routes of Exposure:

Inhalation ,

Target Organs:

Not Applicable,

OSHA Regulatory Status

This product is hazardous according to OSHA 29CFR 1910.1200.

Environment: The environmental hazards and fate of this material have not been characterized.

OTHER INFORMATION No additional information

3 COMPOSITION / INFORMATION ON INGREDIENTS

General information: The formulations for these products are proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the composition table. Active ingredients in any concentration are listed.

Hazardous Component(s):

| Chemical name | CAS-No. | Concentration |
|---------------|--------------|---------------|
| Pembrolizumab | 1374853-91-4 | 10 - <30% |

* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4 FIRST AID MEASURES

Inhalation: Move into fresh air and keep at rest. For breathing difficulties, oxygen may be necessary. Get medical attention. If breathing stops, provide artificial respiration.

Skin contact: Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes.

Eye contact: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: Do not induce vomiting unless directed to do so by medical personnel. Never give liquid to an unconscious person. Get medical attention.

Notes to the physician:

Hazards: See Sections 2 and 11.

Treatment: Treat supportively and symptomatically.

5 FIRE-FIGHTING MEASURES

Extinguishing media: Water spray, fog, CO₂, dry chemical, or alcohol resistant foam.

Unsuitable extinguishing media: None known.

Unusual Fire & Explosion Hazards: Emits toxic fumes under fire conditions.

Special Fire Fighting Procedures: Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Protective Measures: Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

6 ACCIDENTAL RELEASE MEASURES

- Personal precautions:** Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all fire fighting procedures.
- Environmental precautions:** Do not release into the environment.
- Spill Cleanup Methods:** Use a vacuum cleaner. If not possible, moisten dust with water before it is collected with shovel, broom or the like. Collect in containers and seal securely. For waste disposal, see section 13 of the MSDS. Prevent runoff from entering drains, sewers, or streams.

7 HANDLING AND STORAGE

- Handling:** Do not breathe dust. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.
- Storage:** Keep container tightly closed in a cool, well-ventilated place.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION
Exposure limits:

| Chemical name | Type | Exposure Limit values | Source |
|---------------|------|-----------------------|--------|
| Pembrolizumab | TWA | 50 ug/m3 (OEB 3) | Merck |

OEB (Occupational Exposure Band) is an internal Merck control band.

- Protective Measures:** Observe occupational exposure limits and minimize the risk of inhalation of dust. Minimize open handling. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
- Respiratory Protection:** Use an appropriate approved air-purifying respirator equipped with HEPA cartridges/canisters where there is the potential for exceeding established occupational exposure limits or occupational exposure bands. Powered air filter respirator. Use a positive pressure, air-supplied, pressure demand tight fitting respirator (e.g., SCBA or airline equipped with emergency escape bottle) where there is a potential for uncontrolled releases in excess of the respirator's capabilities, where exposure levels are unknown or where air-purifying respirators may not provide adequate protection.
- Hand protection:** Chemical resistant gloves. Consider double gloving.
- Eye protection:** Wear safety glasses with side shields (or goggles). If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Skin and Body Protection:** Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
- Hygiene measures:** Wash skin thoroughly with soap and water.

9 PHYSICAL AND CHEMICAL PROPERTIES**Information on basic physical and chemical properties****Appearance:**

| | |
|------------------------|--------------------|
| Physical State: | Solid |
| Form: | Lyophilized powder |
| Color: | White to off-white |

10 STABILITY AND REACTIVITY

| | |
|--|---|
| Stability: | Stable |
| Possibility of hazardous reactions: | Stable |
| Conditions to avoid: | Excessive heat. Moisture. |
| Incompatible materials: | No data available. |
| Hazardous decomposition products: | Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapors. |

11 TOXICOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.

Specified substance(s):**Acute Toxicity (Oral);**

| Name | Test results |
|---------------|---------------------|
| Pembrolizumab | No data available. |

Acute Toxicity (Dermal):

| Name | Test results |
|---------------|---------------------|
| Pembrolizumab | No data available. |

Acute Toxicity (Inhalation):

| Name | Test results |
|---------------|---------------------|
| Pembrolizumab | No data available. |

Repeated dose toxicity:

| Name | Test results |
|---------------|--|
| Pembrolizumab | NOAEL (Monkey, Intravenous, 30 d, once / week): > 200 mg/kg No significant findings. NOEL (Monkey, Intravenous, 180 d, intermittent): > 200 mg/kg No significant findings. NOAEL (Dog, Intravenous, 180 d, intermittent): 200 mg/kg No significant findings. |

Inhalation: No data available for finished product. Avoid breathing dust.

Ingestion: No data available for finished product.

Skin corrosion/irritation: No data available for finished product.

| | |
|--|--|
| Serious eye damage/eye irritation: | No data available for finished product. Avoid contact with eyes. |
| Respiratory sensitizer/Skin sensitizer: | No data available. |
| Carcinogenicity: | No data available. |
| Mutagenesis: | No data available. |
| Reproductive toxicity: | No data available. |

12 ECOLOGICAL INFORMATION

General information: The environmental hazards and fate of this material have not been characterized.

Ecotoxicity:

Product:

| | |
|---|--------------------|
| Acute toxicity(Fish): | No data available. |
| Chronic Toxicity(Fish): | No data available. |
| Acute toxicity(Aquatic invertebrates): | No data available. |
| Chronic Toxicity(Aquatic invertebrates): | No data available. |
| Acute toxicity(Aquatic plants): | No data available. |
| Persistence and degradability: | No data available. |
| Bioaccumulative potential: | No data available. |
| Mobility: | No data available. |

13 DISPOSAL CONSIDERATIONS

Disposal Methods: Disposal must be in accordance with applicable national, state/provincial, and/or local regulations.

Measures for Avoidance and Recovery: Incineration is the most effective method of disposal in most instances. Do not allow runoff to sewer, waterway or ground. Operations that involve the crushing or shredding of waste materials or returned goods should take into account recommended exposure limits where they exist.

14 TRANSPORT INFORMATION

DOT

Not regulated.

IMDG - International Maritime Dangerous Goods Code

Not regulated.

IATA - International Air Transport Association
Not regulated.

15 REGULATORY INFORMATION

US Regulations

- **CERCLA Hazardous Substance List (40 CFR 302.4):**
None
- **Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3):**
None
- **Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):**
None

SARA Title III

- **Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A):**
None
- **Section 313 Toxic Release Inventory (40 CFR 372):**
None present or none present in regulated quantities.

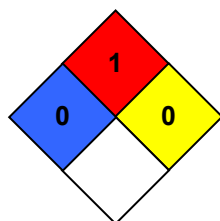
State Regulations

- **California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):**
No ingredient regulated by CA Prop 65 present.
- **Massachusetts Right-To-Know List:**
Sucrose Listed
- **New Jersey Right-To-Know List:**
No ingredient regulated by NJ Right-to-Know Law present.
- **Pennsylvania Right-To-Know List:**
Sucrose Listed

16 OTHER INFORMATION

OTHER INFORMATION

This SDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate SDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

NFPA Hazard ID

Hazard rating: 0 - Minimal; 1 - Slight; 2 - Moderate; 3 - Serious; 4 - Severe

Revision Information:

Not relevant.

Issue Date:

18.09.2014

Disclaimer:

This information is provided without warranty. The information is believed to be correct. This information should be used to make an independent determination of the methods to safeguard workers and the environment.