

**Pembrolizumab / Berahyaluronidase alfa Subcutaneous Formulation**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 4.1     | 15.10.2025     | 7723967-00018 | Date of first issue: 06.01.2021 |

**SECTION 1. IDENTIFICATION**

Product name : Pembrolizumab / Berahyaluronidase alfa Subcutaneous Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : 855 Leandro N. Alem St., 8 Floor  
Buenos Aires, Argentina C1001AFB

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure (Oral) : Category 1 (Immune system)

**GHS label elements**

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H360D May damage the unborn child.  
H372 Causes damage to organs (Immune system) through prolonged or repeated exposure if swallowed.

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 mist or vapors.

## Pembrolizumab / Berahyaluronidase alfa Subcutaneous Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 4.1     | 15.10.2025     | 7723967-00018 | Date of first issue: 06.01.2021 |

P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
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.

### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

### Other hazards which do not result in classification

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

| Chemical name          | CAS-No.      | Concentration (% w/w) |
|------------------------|--------------|-----------------------|
| Pembrolizumab          | 1374853-91-4 | >= 10 -< 20           |
| Sucrose                | 57-50-1      | >= 5 -< 10            |
| Berahyaluronidase alfa | 2636716-20-4 | < 0,1                 |

## SECTION 4. FIRST AID MEASURES

|                                                             |   |                                                                                                                                                                                                                       |
|-------------------------------------------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| General advice                                              | : | In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice.                                                                |
| If inhaled                                                  | : | If inhaled, remove to fresh air.<br>Get medical attention.                                                                                                                                                            |
| In case of skin contact                                     | : | In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact                                      | : | Flush eyes with water as a precaution.<br>Get medical attention if irritation develops and persists.                                                                                                                  |
| If swallowed                                                | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.                                                                                                                 |
| Most important symptoms and effects, both acute and delayed | : | May damage the unborn child.<br>Causes damage to organs through prolonged or repeated exposure if swallowed.                                                                                                          |
| Protection of first-aiders                                  | : | First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment                                                                                                   |

**Pembrolizumab / Berahyaluronidase alfa Subcutaneous Formulation**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
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| 4.1     | 15.10.2025     | 7723967-00018 | Date of first issue: 06.01.2021 |

Notes to physician : when the potential for exposure exists (see section 8).  
: Treat symptomatically and supportively.

**SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

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.

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

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

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.  
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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

## Pembrolizumab / Berahyaluronidase alfa Sub-cutaneous Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 4.1     | 15.10.2025     | 7723967-00018 | Date of first issue: 06.01.2021 |

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.

### SECTION 7. HANDLING AND STORAGE

- |                             |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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.<br>Do not breathe mist or vapors.<br>Do not swallow.<br>Avoid contact with eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Do not eat, drink or smoke when using this product.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Conditions for safe storage | : | Keep in properly labeled containers.<br>Store locked up.<br>Keep tightly closed.<br>Store in accordance with the particular national regulations.                                                                                                                                                                                                                                                                                                                    |
| Materials to avoid          | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives<br>Gases                                                                                                                                                                                                                                                                                                       |

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

| Components                                                       | CAS-No.      | Value type<br>(Form of exposure) | Control parameters / Permissible concentration | Basis    |
|------------------------------------------------------------------|--------------|----------------------------------|------------------------------------------------|----------|
| Pembrolizumab                                                    | 1374853-91-4 | TWA                              | 450 µg/m <sup>3</sup> (OEB 2)                  | Internal |
| Sucrose                                                          | 57-50-1      | CMP                              | 10 mg/m <sup>3</sup>                           | AR OEL   |
| Further information: A4 - Not classifiable as a human carcinogen |              |                                  |                                                |          |
|                                                                  |              | TWA                              | 10 mg/m <sup>3</sup>                           | ACGIH    |
| Berahyaluronidase alfa                                           | 2636716-20-4 | TLV-C                            | 0.06 ug/m <sup>3</sup> (OEB 5)                 | Internal |
| Further information: RSEN                                        |              |                                  |                                                |          |
|                                                                  |              | Wipe limit                       | 0.07 ug/100 cm <sup>2</sup>                    |          |

**Pembrolizumab / Berahyaluronidase alfa Sub-cutaneous Formulation**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 4.1     | 15.10.2025     | 7723967-00018 | Date of first issue: 06.01.2021 |

**Engineering measures** : The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

No open handling permitted.

Totally enclosed processes and materials transport systems are required.

Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

**Personal protective equipment**

**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

**Hand protection**

**Material** : Chemical-resistant gloves

**Remarks** : 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** : Work uniform or laboratory coat.  
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** : 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.

**Pembrolizumab / Berahyaluronidase alfa Subcutaneous Formulation**

|                |                              |                              |                                                                   |
|----------------|------------------------------|------------------------------|-------------------------------------------------------------------|
| Version<br>4.1 | Revision Date:<br>15.10.2025 | SDS Number:<br>7723967-00018 | Date of last issue: 14.04.2025<br>Date of first issue: 06.01.2021 |
|----------------|------------------------------|------------------------------|-------------------------------------------------------------------|

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

|                                                  |                            |
|--------------------------------------------------|----------------------------|
| Appearance                                       | : liquid                   |
| Color                                            | : No data available        |
| Odor                                             | : No data available        |
| Odor Threshold                                   | : No data available        |
| pH                                               | : 5,5<br>No data available |
| 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           |
| Flammability (liquids)                           | : No data available        |
| Upper explosion limit / Upper flammability limit | : No data available        |
| Lower explosion limit / Lower flammability limit | : No data available        |
| Vapor pressure                                   | : No data available        |
| Relative vapor density                           | : No data available        |
| Relative density                                 | : No data available        |
| Density                                          | : No data available        |
| Solubility(ies)<br>Water solubility              | : No data available        |
| Partition coefficient: n-octanol/water           | : Not applicable           |
| Autoignition temperature                         | : No data available        |
| Decomposition temperature                        | : No data available        |

**Pembrolizumab / Berahyaluronidase alfa Sub-cutaneous Formulation**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 4.1     | 15.10.2025     | 7723967-00018 | Date of first issue: 06.01.2021 |

Viscosity  
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 : Not applicable

**SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

**SECTION 11. TOXICOLOGICAL INFORMATION**

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

**Acute toxicity**

Not classified based on available information.

**Components:****Sucrose:**

Acute oral toxicity : LD50 (Rat): 29.700 mg/kg

**Berahyaluronidase alfa:**

Acute oral toxicity : Remarks: Not classified due to lack of data.

Acute inhalation toxicity : Remarks: Not classified due to lack of data.

Acute dermal toxicity : Remarks: Not classified due to lack of data.

**Skin corrosion/irritation**

Not classified based on available information.

**Pembrolizumab / Berahyaluronidase alfa Sub-cutaneous Formulation**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 4.1     | 15.10.2025     | 7723967-00018 | Date of first issue: 06.01.2021 |

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**Components:****Berahyaluronidase alfa:**

Remarks : Not classified due to lack of data.

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Berahyaluronidase alfa:**

Remarks : Not classified due to lack of data.

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Berahyaluronidase alfa:**

Result : Sensitizer

**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**Berahyaluronidase alfa:**

Genotoxicity in vitro : Remarks: Not classified due to lack of data.

Genotoxicity in vivo : Remarks: Not classified due to lack of data.

Germ cell mutagenicity - : May cause genetic defects.  
Assessment**Carcinogenicity**

Not classified based on available information.

**Components:****Berahyaluronidase alfa:**

Remarks : Not classified due to lack of data.

**Pembrolizumab / Berahyaluronidase alfa Subcutaneous Formulation**

|                |                              |                              |                                                                   |
|----------------|------------------------------|------------------------------|-------------------------------------------------------------------|
| Version<br>4.1 | Revision Date:<br>15.10.2025 | SDS Number:<br>7723967-00018 | Date of last issue: 14.04.2025<br>Date of first issue: 06.01.2021 |
|----------------|------------------------------|------------------------------|-------------------------------------------------------------------|

**Reproductive toxicity**

May damage the unborn child.

**Components:****Pembrolizumab:**

Reproductive toxicity - Assessment : May damage the unborn child., Based on data from similar materials

**Berahyaluronidase alfa:**

Effects on fertility : Remarks: Not classified due to lack of data.  
May cause adverse reproductive effects.

Effects on fetal development : Remarks: Not classified due to lack of data.  
May cause birth defects.

Reproductive toxicity - Assessment : May damage fertility. May damage the unborn child.

**STOT-single exposure**

Not classified based on available information.

**Components:****Berahyaluronidase alfa:**

Assessment : May cause damage to organs.  
Remarks : Not classified due to lack of data.

**STOT-repeated exposure**

Causes damage to organs (Immune system) through prolonged or repeated exposure if swallowed.

**Components:****Pembrolizumab:**

Target Organs : Immune system  
Assessment : Causes damage to organs through prolonged or repeated exposure.

**Berahyaluronidase alfa:**

Assessment : May cause damage to organs through prolonged or repeated exposure.  
Remarks : Not classified due to lack of data.

**Repeated dose toxicity****Components:****Pembrolizumab:**

Species : Monkey  
NOAEL : 200 mg/kg  
Application Route : Intravenous

**Pembrolizumab / Berahyaluronidase alfa Subcutaneous Formulation**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 4.1     | 15.10.2025     | 7723967-00018 | Date of first issue: 06.01.2021 |

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

**Berahyaluronidase alfa:**

Remarks : Not classified due to lack of data.  
May cause damage to organs.

**Aspiration toxicity**

Not classified based on available information.

**Components:****Berahyaluronidase alfa:**

Not applicable

**Experience with human exposure****Components:****Pembrolizumab:**

Inhalation : Target Organs: Immune system  
Symptoms: Cough, Fatigue, Nausea, pruritis, Rash, constipation, joint pain, Diarrhea, 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

**Berahyaluronidase alfa:**

General Information : Avoid repeated exposure.  
May cause eye, skin, and respiratory tract irritation.  
May be harmful if swallowed.  
May be harmful if inhaled.  
May produce an allergic reaction.  
May cause heritable genetic damage.  
May cause adverse reproductive effects.  
May cause birth defects.  
May cause damage to organs.

**Further information****Components:****Berahyaluronidase alfa:**

Remarks : The toxicological properties of this material have not been fully investigated

**Pembrolizumab / Berahyaluronidase alfa Subcutaneous Formulation**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 4.1     | 15.10.2025     | 7723967-00018 | Date of first issue: 06.01.2021 |

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Berahyaluronidase alfa:**

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae/aquatic plants : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available

**Ecotoxicology Assessment**

Acute aquatic toxicity : No data available

Chronic aquatic toxicity : No data available

**Persistence and degradability****Components:****Berahyaluronidase alfa:**

Biodegradability : Remarks: No data available

Stability in water : Remarks: No data available

**Bioaccumulative potential****Components:****Sucrose:**

Partition coefficient: n-octanol/water : Pow: &lt; 1

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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**SECTION 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

**Pembrolizumab / Berahyaluronidase alfa Subcutaneous Formulation**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 4.1     | 15.10.2025     | 7723967-00018 | Date of first issue: 06.01.2021 |

handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

**SECTION 14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

Not regulated as a dangerous good

**MERCOSUR**

Not regulated as a dangerous good

**IATA-DGR**

Not regulated as a dangerous good

**IMDG-Code**

Not regulated as a dangerous good

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

Not applicable for product as supplied.

**Special precautions for user**

Not applicable

**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

**The ingredients of this product are reported in the following inventories:**

CA. DSL : not determined

AICS : not determined

IECSC : not determined

**SECTION 16. OTHER INFORMATION**

Revision Date : 15.10.2025  
Date format : dd.mm.yyyy

**Further information**

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

**Pembrolizumab / Berahyaluronidase alfa Subcutaneous Formulation**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 4.1     | 15.10.2025     | 7723967-00018 | Date of first issue: 06.01.2021 |

**Full text of other abbreviations**

|        |   |                                         |
|--------|---|-----------------------------------------|
| ACGIH  | : | USA. ACGIH Threshold Limit Values (TLV) |
| AR OEL | : | Argentina. Occupational Exposure Limits |

|              |   |                               |
|--------------|---|-------------------------------|
| ACGIH / TWA  | : | 8-hour, time-weighted average |
| AR OEL / CMP | : | TLV (Threshold Limit Value)   |

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 Standardization; 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 Organization 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; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; 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 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, Authorization 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

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.

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