



# SAFETY DATA SHEET

## 1. Identification

### Product identifier

**Mimrylo (lyophilized powder vial)**

### Other means of identification

#### Synonyms

Mimrylo (rusfertide) for injection, Rusfertide drug product, TAK-121, PTG-300

### Recommended use

Pharmaceutical product.

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

### Recommended restrictions

All other uses.

### Manufacturer/Importer/Supplier/Distributor information

#### Main Office

Takeda Pharmaceutical Company Limited  
1-1, Nihonbashi-Honcho 2-chome, Chuo-ku, Tokyo 103-8668, Japan

## SDS Information

### US Office

500 Kendall Street, Cambridge, MA 02142, USA

### CH Office

Thurgauerstrasse 130, 8152 Glattpark-Opfikon (Zurich), Switzerland

### E-mail

Takeda-SDS@takeda.com

### Emergency phone number

Call CHEMTREC Day or Night  
Within USA and Canada: 1-800-424-9300  
Outside USA and Canada: +1 703-741-5970 (collect calls accepted)  
From anywhere in the world: +1 703-527-3887

### Note)

When calling Chemtrec for emergency, first tell the product name on SDS along with the SDS date.

### Note)

When transcribing the Chemtrec number to GHS label or others, the above note must be transcribed together.

## 2. Hazard(s) identification

### Hazards of the product as supplied

#### Physical hazards

Not classified.

#### Health hazards

|                                                   |                                           |
|---------------------------------------------------|-------------------------------------------|
| Carcinogenicity                                   | Category 2                                |
| Reproductive toxicity (the unborn child)          | Category 2                                |
| Specific target organ toxicity, repeated exposure | Category 2 (Bone marrow, Lymphoid system) |

#### OSHA defined hazards

Combustible dust

#### Other hazards

#### Hazard(s) not otherwise classified (HNOC)

No additional hazards are known to be associated with the expected conditions of use at the time of publication. This document does not address hazards that may arise from uses not reasonably anticipated by the manufacturer.

## Label elements

**Signal word**

Warning

**Hazard statement**

Suspected of causing cancer. Suspected of damaging the unborn child. May cause damage to organs (Bone marrow, Lymphoid system) through prolonged or repeated exposure. May form combustible dust concentrations in air.

**Precautionary statement****Prevention**

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust. Wear protective gloves/protective clothing/eye protection/face protection.

**Response**

IF exposed or concerned: Get medical advice/attention.

**Storage**

Store locked up.

**Disposal**

Dispose of contents/container in accordance with local/regional/national/international regulations.

### 3. Composition/information on ingredients

**Mixtures**

| Chemical name             | CAS number   | %           |
|---------------------------|--------------|-------------|
| Rusfertide                | 1628323-80-7 | >26 - <72   |
| D-Mannitol                | 69-65-8      | > 26 - <70  |
| Sodium acetate trihydrate | 6131-90-4    | >1.8 - <3.8 |

**Composition comments**

All concentrations are in percent by weight.  
Sodium hydroxide was used for pH adjustment.

### 4. First-aid measures

**Inhalation**

Move to fresh air. Call a physician if symptoms develop or persist.

**Skin contact**

Wash off with soap and water. Get medical attention if irritation develops and persists.

**Eye contact**

Do not rub eyes. Rinse with water. Get medical attention if irritation develops and persists.

**Ingestion**

Rinse mouth. Get medical attention if symptoms occur.

**Most important symptoms/effects, acute and delayed**

Dusts may irritate the respiratory tract, skin and eyes. Prolonged exposure may cause chronic effects.

**Indication of immediate medical attention and special treatment needed**

Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

**General information**

IF exposed or concerned: Get medical advice/attention. If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

### 5. Fire-fighting measures

**Suitable extinguishing media**

Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture. Water fog. Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>). Apply extinguishing media carefully to avoid creating airborne dust.

**Unsuitable extinguishing media**

Do not use water jet as an extinguisher, as this will spread the fire.

**Specific hazards arising from the chemical**

Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard. During fire, gases hazardous to health may be formed.

**Special protective equipment and precautions for firefighters**

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

|                                             |                                                                                                                                                                                                                 |
|---------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Fire fighting equipment/instructions</b> | Use standard firefighting procedures and consider the hazards of other involved materials. In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk. |
| <b>General fire hazards</b>                 | May form combustible dust concentrations in air.                                                                                                                                                                |

## 6. Accidental release measures

|                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|----------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Personal precautions, protective equipment and emergency procedures</b> | Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Use only non-sparking tools. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Wear appropriate protective equipment and clothing during clean-up. Do not breathe dust. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.                                                                                                                                                           |
| <b>Methods and materials for containment and cleaning up</b>               | <p>Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Take precautionary measures against static discharge. Use only non-sparking tools. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Collect dust using a vacuum cleaner equipped with HEPA filter. Stop the flow of material, if this is without risk.</p> <p>Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Following product recovery, flush area with water.</p> <p>Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal.</p> <p>Never return spills to original containers for re-use. Put material in suitable, covered, labeled containers. For waste disposal, see section 13 of the SDS.</p> |
| <b>Environmental precautions</b>                                           | Avoid discharge into drains, water courses or onto the ground.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

## 7. Handling and storage

|                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|---------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Precautions for safe handling</b>                                | Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Minimize dust generation and accumulation. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Combustible dust clouds may be created where operations produce fine material (dust). Handling and processing operations should be conducted in accordance with 'best practices' (e.g. NFPA-654). Explosion-proof general and local exhaust ventilation. Do not breathe dust. Pregnant or breastfeeding women must not handle this product. Should be handled in closed systems, if possible. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. |
| <b>Conditions for safe storage, including any incompatibilities</b> | Store locked up. Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS). When quality control required, follow the storage condition specified separately.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

## 8. Exposure controls/personal protection

|                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Occupational exposure limits</b>     | See Exposure guidelines.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Biological limit values</b>          | No biological exposure limits noted for the ingredient(s).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Exposure guidelines</b>              | Rusfertide: OEL - 40 µg/m <sup>3</sup> (Takeda internal value).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Appropriate engineering controls</b> | Explosion-proof general and local exhaust ventilation. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Use only appropriately classified electrical equipment and powered industrial trucks. |

**Individual protection measures, such as personal protective equipment**

|                               |                                                                                                                                                                                                                                                                                                                                                   |
|-------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Eye/face protection</b>    | Wear safety glasses or safety goggles unless full face respirator is in use.                                                                                                                                                                                                                                                                      |
| <b>Skin protection</b>        |                                                                                                                                                                                                                                                                                                                                                   |
| <b>Hand protection</b>        | Wear appropriate chemical resistant gloves.<br>Impervious oil/water/chemical-resistant gloves (nitrile, etc.).<br>Gloves meeting EN374, ASTM F1001 or international equivalent standard are recommended.                                                                                                                                          |
| <b>Skin protection</b>        |                                                                                                                                                                                                                                                                                                                                                   |
| <b>Other</b>                  | Wear suitable protective clothing. Use of an impervious apron is recommended.                                                                                                                                                                                                                                                                     |
| <b>Respiratory protection</b> | Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA 29 CFR 1910.134. Seek advice from supervisor on the company's respiratory protection standards. |
| <b>Thermal hazards</b>        | Wear appropriate thermal protective clothing, when necessary.                                                                                                                                                                                                                                                                                     |

**General hygiene considerations** Observe any medical surveillance requirements. When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

**9. Physical and chemical properties**

|                                                                 |                                                  |
|-----------------------------------------------------------------|--------------------------------------------------|
| <b>Physical state</b>                                           | Solid.                                           |
| <b>Form</b>                                                     | Lyophilized cake.                                |
| <b>Color</b>                                                    | White to off-white.                              |
| <b>Odor</b>                                                     | Property has not been measured.                  |
| <b>Odor threshold</b>                                           | Property has not been measured.                  |
| <b>Melting point/freezing point</b>                             | Property has not been measured.                  |
| <b>Boiling point or initial boiling point and boiling range</b> | Property has not been measured.                  |
| <b>Flammability</b>                                             | May form combustible dust concentrations in air. |
| <b>Upper/lower flammability or explosive limits</b>             |                                                  |
| <b>Explosive limit - lower (%)</b>                              | Not applicable, material is a solid.             |
| <b>Explosive limit - upper (%)</b>                              | Not applicable, material is a solid.             |
| <b>Flash point</b>                                              | Not applicable, material is a solid.             |
| <b>Auto-ignition temperature</b>                                | Not applicable, material is a solid.             |
| <b>Decomposition temperature</b>                                | Property has not been measured.                  |
| <b>pH</b>                                                       | > 4.9 - < 6.9 (reconstituted solution.)          |
| <b>Kinematic viscosity</b>                                      | Not applicable, material is a solid.             |
| <b>Solubility</b>                                               |                                                  |
| <b>Solubility (water)</b>                                       | Property has not been measured.                  |
| <b>Partition coefficient (n-octanol/water)</b>                  | Not applicable to mixtures.                      |
| <b>Vapor pressure</b>                                           | Not applicable, material is a solid.             |
| <b>Density and/or relative density</b>                          |                                                  |
| <b>Density</b>                                                  | Property has not been measured.                  |
| <b>Relative density</b>                                         | Property has not been measured.                  |
| <b>Vapor density</b>                                            | Not applicable, material is a solid.             |
| <b>Particle characteristics</b>                                 | Property has not been measured.                  |
| <b>Other information</b>                                        |                                                  |
| <b>Evaporation rate</b>                                         | Property has not been measured.                  |
| <b>Explosive properties</b>                                     | Not explosive.                                   |
| <b>Oxidizing properties</b>                                     | Not oxidizing.                                   |
| <b>Viscosity</b>                                                | Not applicable, material is a solid.             |

## 10. Stability and reactivity

|                                           |                                                                                                                             |
|-------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| <b>Reactivity</b>                         | The product is stable and non-reactive under normal conditions of use, storage and transport.                               |
| <b>Chemical stability</b>                 | Material is stable under normal conditions.                                                                                 |
| <b>Possibility of hazardous reactions</b> | No dangerous reaction known under conditions of normal use.                                                                 |
| <b>Conditions to avoid</b>                | Keep away from heat, sparks and open flame. Contact with incompatible materials. Minimize dust generation and accumulation. |
| <b>Incompatible materials</b>             | Strong oxidizing agents.                                                                                                    |
| <b>Hazardous decomposition products</b>   | No hazardous decomposition products are known.                                                                              |

## 11. Toxicological information

### Information on likely routes of exposure

|                     |                                       |
|---------------------|---------------------------------------|
| <b>Inhalation</b>   | Dust may irritate respiratory system. |
| <b>Skin contact</b> | Dust or powder may irritate the skin. |
| <b>Eye contact</b>  | Dust may irritate the eyes.           |
| <b>Ingestion</b>    | May cause discomfort if swallowed.    |

|                                                                                     |                                                                                                        |
|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| <b>Symptoms related to the physical, chemical and toxicological characteristics</b> | Prolonged exposure may cause chronic effects. Dusts may irritate the respiratory tract, skin and eyes. |
|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|

### Information on toxicological effects

|                               |                                   |
|-------------------------------|-----------------------------------|
| <b>Acute toxicity</b>         | Not expected to be acutely toxic. |
| Rusfertide (CAS 1628323-80-7) | Result: No data available         |

|                                    |                            |
|------------------------------------|----------------------------|
| <b>Skin corrosion/irritation</b>   | Not classifiable.          |
| <b>Irritation Corrosion - Skin</b> |                            |
| Rusfertide (CAS 1628323-80-7)      | Result: No data available. |

|                                          |                            |
|------------------------------------------|----------------------------|
| <b>Serious eye damage/eye irritation</b> | Not classifiable.          |
| <b>Eye</b>                               |                            |
| Rusfertide (CAS 1628323-80-7)            | Result: No data available. |

### Respiratory or skin sensitization

|                                  |                            |
|----------------------------------|----------------------------|
| <b>Respiratory sensitization</b> | Not classifiable.          |
| Rusfertide (CAS 1628323-80-7)    | Result: No data available. |
| <b>Skin sensitization</b>        | Not classifiable.          |
| <b>Skin sensitization</b>        |                            |
| Rusfertide (CAS 1628323-80-7)    | Result: No data available. |

|                               |                 |
|-------------------------------|-----------------|
| <b>Germ cell mutagenicity</b> | Not classified. |
|-------------------------------|-----------------|

|                               |                                                                                                                                                                                                                                  |
|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Mutagenicity</b>           |                                                                                                                                                                                                                                  |
| Rusfertide (CAS 1628323-80-7) | Result: Rusfertide is not genotoxic based on in vitro assays, Reverse mutation bacterial (Ames) assay and chromosome aberration assay in human peripheral blood lymphocytes, and in in vivo chromosome aberration assay in rats. |

|                               |                                                                                                                                                                             |
|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Carcinogenicity</b>        | Suspected of causing cancer.                                                                                                                                                |
| Rusfertide (CAS 1628323-80-7) | Result: 1. rasH2 transgenic mouse (26-week), SC lowest effect dose: 6.25 mg/kg/week in males and 12.5 mg/kg/week in females.<br>Result: 2. Effects: skin/subcutis neoplasm. |

### IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

### NTP Report on Carcinogens

Not listed.

## OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

### Reproductive toxicity

Suspected of damaging the unborn child.

#### Reproductivity

Rusfertide (CAS 1628323-80-7)

Result: 1. Nonclinical studies show that rusfertide has the potential to cause embryo-fetal toxicity in the absence of maternal toxicity:  
Result: 2. Fertility and early embryonic development (FEED) toxicity study, Female Rat, SC NOAEL: 3 mg/kg/week (highest dose tested).  
Effects: no effects on female fertility and early embryonic development.  
Result: 3. Fertility and early embryonic development (FEED) toxicity study, Male Rat, SC NOAEL: 10 mg/kg/week (highest dose tested)  
Effects: no effects on male fertility and early embryonic development.  
Result: 4. Definitive embryo-fetal development toxicity study, Rat, SC NOAEL (maternal): 3 mg/kg/dose (highest dose tested).  
Effects: anemia  $\geq 1$  mg/kg/dose (exaggerated pharmacology effect)  
Result: 5. Definitive embryo-fetal development toxicity study, Rat, SC NOAEL (developmental): 0.3 mg/kg/dose  
Effects: structural abnormalities at  $\geq 1$  mg/kg/dose.  
Result: 6. Definitive embryo-fetal development toxicity study, Rabbit, SC NOAEL (maternal): 1 mg/kg/dose (highest dose tested).  
Effects: anemia at all doses (exaggerated pharmacology effect)  
Result: 7. Definitive embryo-fetal development toxicity study, Rabbit, SC NOAEL (developmental): 0.3 mg/kg/dose  
Effects: embryo lethality at 1 mg/kg/dose (highest dose tested).

### Specific target organ toxicity - single exposure

Not classifiable.

Rusfertide (CAS 1628323-80-7)

Result: 1. Rat, subcutaneous (SC) maximum tolerated dose = 300 mg/kg, lowest effect level (pharmacological effects) = 30 mg/kg/day  
Result: 2. Effects: reduction in hemoglobin levels and changes in red blood cell parameters (expected pharmacological effects.)

### Specific target organ toxicity - repeated exposure

May cause damage to organs (Bone marrow, Lymphoid system) through prolonged or repeated exposure.

Rusfertide (CAS 1628323-80-7)

Result: 1. Rat (26-week), SC lowest effect dose: 1 mg/kg/week.  
Result: 2. Effects: hematopoietic hypercellularity in bone marrow and hepatic and splenic extramedullary hematopoiesis; reduction in red blood cell parameters and anemia, decreased body weight gain at 3 mg/kg/week.  
Result: 3. Rat (26-week), SC NOAEL for systemic toxicity: 10 mg/kg/week.  
Result: 4. Monkey (39-week), SC lowest effect dose: 0.6 mg/kg/week  
Result: 5. Effects: reduction in red blood cell parameters and anemia; hematopoietic hypercellularity in bone marrow and hepatic and splenic extramedullary hematopoiesis at 2 mg/kg/week.  
Result: 6. Monkey (39-week), SC NOAEL for systemic toxicity: 2 mg/kg/week.

### Aspiration hazard

Not relevant, due to the form of the product.

**Chronic effects** May cause damage to organs through prolonged or repeated exposure.

## 12. Ecological information

**Ecotoxicity** Not expected to be harmful to aquatic organisms.

**Persistence and degradability** No data is available on the degradability of this product.

**Bioaccumulative potential** No data available.

**Mobility in soil** No data available.

**Other adverse effects** No data available.

## 13. Disposal considerations

**Disposal instructions** Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations.

**Local disposal regulations** Dispose in accordance with all applicable regulations.

**Hazardous waste code** The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

**Waste from residues / unused products** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner.

**Contaminated packaging** Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

## 14. Transport information

**DOT**  
Not regulated as dangerous goods.

**IATA**  
Not regulated as dangerous goods.

**IMDG**  
Not regulated as dangerous goods.

**Transport in bulk according to IMO instruments** Not applicable.

## 15. Regulatory information

**US federal regulations** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.  
All components are listed on or exempt from the U.S. EPA TSCA Inventory List.  
This product may only be used for TSCA Exempt purposes such as R&D or Food, Drug or Cosmetic use.

**Toxic Substances Control Act (TSCA)** All components are either listed on the TSCA 8(b) inventory and designated "active" or exempt from listing.

### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

### SARA 304 Emergency release notification

Not regulated.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### SARA 302 Extremely hazardous substance

Not listed.

**SARA 311/312 Hazardous chemical** Yes

**Classified hazard categories**

Combustible dust  
Carcinogenicity  
Reproductive toxicity  
Specific target organ toxicity (single or repeated exposure)

**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)**

Not regulated.

**US state regulations****US. Massachusetts RTK - Substance List**

Not regulated.

**US. New Jersey Worker and Community Right-to-Know Act**

Not listed.

**US. Pennsylvania Worker and Community Right-to-Know Law**

Not listed.

**US. Rhode Island RTK**

Not regulated.

**California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

**16. Other information, including date of preparation or last revision**

**Issue date** 27-July-2026

**Revision date** -

**Version #** 01

**Further information** Refer to:  
OSHA 3371-08 2009, Hazard Communication Guidance for Combustible Dusts  
NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids

**References** IARC Monographs. Overall Evaluation of Carcinogenicity  
In-house data.

**Disclaimer** Takeda Pharmaceutical Company Limited cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.