

## SAFETY DATA SHEET

According to JIS Z 7253:2019  
Revision Date 15-Apr-2021  
Version 2.01

## Section 1: PRODUCT AND COMPANY IDENTIFICATION

Product name	Insulin Glargine, recombinant
Product code	092-06181,098-06183

Manufacturer	FUJIFILM Wako Pure Chemical Corporation 1-2 Doshomachi 3-Chome Chuo-ku, Osaka 540-8605, Japan Phone: +81-6-6203-3741 Fax: +81-6-6203-5964
Supplier	FUJIFILM Wako Pure Chemical Corporation 1-2 Doshomachi 3-Chome, Chuo-ku, Osaka 540-8605, Japan Phone: +81-6-6203-3741 Fax: +81-6-6203-2029
Emergency telephone number	+81-6-6203-3741 / +81-3-3270-8571
Recommended uses and restrictions on use	For research use only

## Section 2: HAZARDS IDENTIFICATION

## GHS classification

Classification of the substance or mixture

Not a hazardous substance or mixture according to the Globally Harmonized System (GHS)

## Pictograms

Signal word none

## Hazard statements

Not a hazardous substance or mixture according to the Globally Harmonized System (GHS)

## Precautionary statements-(Prevention)

- Not applicable

## Precautionary statements-(Response)

- Not applicable

## Precautionary statements-(Storage)

- Not applicable

## Precautionary statements-(Disposal)

- Not applicable

## Others

Other hazards Not available

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

Single Substance or Mixture Substance

Formula C267H404N72O78S6

Chemical Name	Weight-%	Molecular weight	ENCS	ISHL No.	CAS RN
Insulin Glargine, recombinant	95.0	6062.89	N/A	N/A	160337-95-1

**Impurities and/or Additives :** Not applicable  
**Source** Pichia Pastoris expressed insulin glargine

## Section 4: FIRST AID MEASURES

### Inhalation

Remove to fresh air. If symptoms persist, call a physician.

### Skin contact

Wash off immediately with soap and plenty of water. If symptoms persist, call a physician.

### Eye contact

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediate medical attention is required.

### Ingestion

Rinse mouth. Never give anything by mouth to an unconscious person. Call a physician or poison control center immediately. Do not induce vomiting without medical advice.

### Protection of first-aiders

Use personal protective equipment as required.

## Section 5: FIRE FIGHTING MEASURES

### Suitable extinguishing media

Water spray (fog), Carbon dioxide (CO<sub>2</sub>), Foam, Extinguishing powder, Sand

### Unsuitable extinguishing media

No information available

### Specific hazards arising from the chemical product

Thermal decomposition can lead to release of irritating and toxic gases and vapors.

### Special extinguishing method

No information available

### Special protective actions for fire-fighters

Use personal protective equipment as required. Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

## Section 6: ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures

For indoor, provide adequate ventilation process until the end of working. Deny unnecessary entry other than the people involved by, for example, using a rope. While working, wear appropriate protective equipments to avoid adhering it on skin, or inhaling the gas. Work from windward, and retract the people downwind.

### Environmental precautions

To be careful not discharged to the environment without being properly handled waste water contaminated.

### Methods and materials for contaminant and methods and materials for cleaning up

Sweep up and gather scattered particles, and collect it in an empty airtight container.

### Recovery, neutralization

No information available

### Secondary disaster prevention measures

Clean contaminated objects and areas thoroughly observing environmental regulations.

## Section 7: HANDLING AND STORAGE

### Handling

#### Technical measures

Avoid contact with strong oxidizing agents. Be careful to hygroscopic. Use with local exhaust ventilation.

#### Precautions

Do not rough handling containers, such as upsetting, falling, giving a shock, and dragging. Prevent leakage, overflow, and scattering. Not to generate steam and dust in vain. Seal the container after use. After handling, wash hands and face, and then gargle. In places other than those specified, should not be smoking or eating and drinking. Should not be brought

contaminated protective equipment and gloves to rest stops. Deny unnecessary entry of non-emergency personnel to the handling area.

**Safety handling precautions**

Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

**Storage****Safe storage conditions****Storage conditions**

Container protected from light, and store tightly closed in freezer (-20°C). Protect from moisture.

**Safe packaging material**

Glass

**Incompatible substances**

Strong oxidizing agents

## Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

**Engineering controls**

In case of indoor workplace, seal the source or use a local exhaust system. Provide the safety shower facility, and hand- and eye-wash facility. And display their position clearly.

**Exposure limits**

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

**Personal protective equipment****Respiratory protection**

Dust mask

**Hand protection**

Protection gloves

**Eye protection**

protective eyeglasses or chemical safety goggles

**Skin and body protection**

Long-sleeved work clothes

**General hygiene considerations**

Handle in accordance with good industrial hygiene and safety practice.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

**Form****Color**

White - nearly white

**Appearance**

crystals - powder

**Odor**

No data available

**Melting point/freezing point**

No data available

**Boiling point, initial boiling point and boiling range**

No data available

**Flammability**

No data available

**Evaporation rate:**

No data available

**Flammability (solid, gas):**

No data available

**Upper/lower flammability or explosive limits****Upper :**

No data available

**Lower :**

No data available

**Flash point**

No data available

**Auto-ignition temperature:**

No data available

**Decomposition temperature:**

No data available

**pH**

No data available

**Viscosity (coefficient of viscosity)**

No data available

**Dynamic viscosity**

No data available

**Solubilities**

Dilute Hydrochloric Acid : soluble . water , Ethanol , Diethyl ether and chloroform : practically insoluble,or insoluble .

**n-Octanol/water partition coefficient:(log Pow)**

No data available

**Vapour pressure**

No data available

**Specific Gravity / Relative density**

No data available

**Vapour density**

No data available

**Particle characteristics**

No data available

## Section 10: STABILITY AND REACTIVITY

**Stability**

<b>Reactivity</b>	No data available
<b>Chemical stability</b>	May be altered by light. Hygroscopic.
<b>Hazardous reactions</b>	None under normal processing
<b>Conditions to avoid</b>	Extremes of temperature and direct sunlight, Moisture
<b>Incompatible materials</b>	Strong oxidizing agents
<b>Hazardous decomposition products</b>	Carbon monoxide (CO), Carbon dioxide (CO <sub>2</sub> ), Nitrogen oxides (NO <sub>x</sub> ), Sulfur oxides (SO <sub>x</sub> )

### Section 11: TOXICOLOGICAL INFORMATION

<b>Acute toxicity</b>	No data available
<b>Skin irritation/corrosion</b>	No data available
<b>Serious eye damage/ irritation</b>	No data available
<b>Respiratory or skin sensitization</b>	No data available
<b>Reproductive cell mutagenicity</b>	No data available
<b>Carcinogenicity</b>	No data available
<b>Reproductive toxicity</b>	No data available
<b>STOT-single exposure</b>	No data available
<b>STOT-repeated exposure</b>	No data available
<b>Aspiration hazard</b>	No data available

### Section 12: ECOLOGICAL INFORMATION

<b>Ecotoxicity</b>	No information available
<b>Other data</b>	No data available
<b>Persistence and degradability</b>	No information available
<b>Bioaccumulative potential</b>	No information available
<b>Mobility in soil</b>	No information available
<b>Hazard to the ozone layer</b>	No information available

### Section 13: DISPOSAL CONSIDERATIONS

<b>Waste from residues</b>	Disposal should be in accordance with applicable regional, national and local laws and regulations.
<b>Contaminated container and contaminated packaging</b>	Disposal should be in accordance with applicable regional, national and local laws and regulations.

### Section 14: TRANSPORT INFORMATION

<b>ADR/RID</b>	Not regulated
<b>UN number</b>	-
<b>Proper shipping name:</b>	
<b>UN classification</b>	
<b>Subsidiary hazard class</b>	
<b>Packing group</b>	
<b>Marine pollutant</b>	Not applicable
<b>IMDG</b>	Not regulated
<b>UN number</b>	-

<b>Proper shipping name:</b>	
<b>UN classification</b>	
<b>Subsidiary hazard class</b>	
<b>Packing group</b>	
<b>Marine pollutant (Sea)</b>	Not applicable
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	No information available
<b>IATA</b>	Not regulated
<b>UN number</b>	-
<b>Proper shipping name:</b>	
<b>UN classification</b>	
<b>Subsidiary hazard class</b>	
<b>Packing group</b>	
<b>Environmentally Hazardous Substance</b>	Not applicable

## Section 15: REGULATORY INFORMATION

### International Inventories

<b>EINECS/ELINCS</b>	-
<b>TSCA</b>	-

### Japanese regulations

<b>Fire Service Act</b>	Not applicable
<b>Poisonous and Deleterious Substances Control Law</b>	Not applicable
<b>Industrial Safety and Health Act</b>	Not applicable
<b>Regulations for the carriage and storage of dangerous goods in ship</b>	Not applicable
<b>Civil Aeronautics Law</b>	Not applicable
<b>Pollutant Release and Transfer Register Law</b>	Not applicable
<b>Export Trade Control Order</b>	Not applicable

## Section 16: OTHER INFORMATION

### **Key literature references and sources for data etc.**

NITE: National Institute of Technology and Evaluation (JAPAN)  
<http://www.safe.nite.go.jp/japan/db.html>  
 IATA dangerous Goods Regulations  
 RTECS:Registry of Toxic Effects of Chemical Substances  
 Japan Industrial Safety and Health Association GHS Model SDS  
 Dictionary of Synthetic Organic Chemistry, SSOCJ, Koudansha Scientific Co.Ltd.  
 Chemical Dictionary, Kyouritsu Publishing Co., Ltd.  
 etc

### **Disclaimer**

This SDS is according to JIS Z 7253: 2019. 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 given is designed only as a guidance for safe handling, and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

GHS Classification is according to JIS Z7252(2019). \*JIS: Japanese Industrial Standards

**End of Safety Data Sheet**