

SAFETY DATA SHEET

According to JIS Z 7253:2019
Revision date 09-Feb-2023
Revision Number 2.02

Section 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name	Insulin Solution, Human, recombinant
Product Code	093-06351

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**

Serious eye damage/eye irritation

Category 2B

Pictograms**Signal word**

Warning

Hazard statements

Central nervous system

Precautionary statements-(Prevention)

- Wash face, hands and any exposed skin thoroughly after handling

Precautionary statements-(Response)

- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
- If eye irritation persists: Get medical advice/attention

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 Mixture

Chemical Name	Weight-%	Molecular weight	ENCS	ISHL No.	CAS RN
Water	99	18.02	N/A	N/A	7732-18-5
Insulin Solution, Human, recombinant	1	N/A	N/A	N/A	N/A-09-0635

Note on ISHL No.:	* in the table means announced chemical substances.
Impurities and/or Additives:	Not applicable
Source	Pichia pastoris expressed human insulin
Substances Remarks:	The composition considered to be hazardous are listed in the above. The remaining ingredients are not hazardous substances, or exist at below reportable level.

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

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment

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

Absorb dry sand, earth, sawdust and the waste. Collect empty container that can be sealed.

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

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 Store away from sunlight in cold (-20°C). Keep container tightly closed.

Safe packaging material Polyethylene terephthalate

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 Protective 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 colorless

Turbidity clear

Appearance liquid

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

8.0 - 9.0

Viscosity (coefficient of viscosity)

no data available

Dynamic viscosity

no data available

Solubilities

water : miscible

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

Reactivity no data available

Chemical stability Stable under recommended storage conditions.

Hazardous reactions

None under normal processing

Conditions to avoid

Extremes of temperature and direct sunlight

Incompatible materials

Strong oxidizing agents

Hazardous decomposition products

Carbon monoxide (CO), Carbon dioxide (CO₂), Nitrogen oxides (NO_x)

Section 11: TOXICOLOGICAL INFORMATION

Acute toxicity no data available

Skin irritation/corrosion no data available

Serious eye damage/ irritation no data available

Respiratory or skin sensitization no data available

Reproductive cell mutagenicity no data available

Carcinogenicity no data available

Reproductive toxicity no data available

STOT-single exposure no data available

STOT-repeated exposure no data available

Aspiration hazard no data available

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity No information available

Other data no data available

Persistence and degradability No information available

Bioaccumulative potential No information available

Mobility in soil No information available

Hazard to the ozone layer No information available

Section 13: DISPOSAL CONSIDERATIONS

Waste from residues

Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated container and contaminated packaging

Disposal should be in accordance with applicable regional, national and local laws and regulations.

Section 14: TRANSPORT INFORMATION

ADR/RID Not regulated

UN number -

Proper shipping name:

UN classification

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

Section 15: REGULATORY INFORMATION

International Inventories

EINECS/ELINCS	Listed
TSCA	Listed

Japanese regulations

Fire Service Act	Not applicable
Poisonous and Deleterious Substances Control Law	Not applicable
Industrial Safety and Health Act	Not applicable
Regulations for the carriage and storage of dangerous goods in ship	Not applicable
Civil Aeronautics Law	Not applicable
Pollutant Release and Transfer Register Law (~2023.3.31)	Not applicable
Pollutant Release and Transfer Register Law (2023/4/1~)	Not applicable
Export Trade Control Order	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