

## SAFETY DATA SHEET

According to JIS Z 7253:2019  
Revision date 08-Aug-2024  
Revision Number 1.04

## Section 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name	Lactose Hydrate
Product Code	121-06685

**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** Pharmaceuticals raw materials

**Restrictions on use** Seek expert judgment when using for purposes other than those recommended.

## 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** C<sub>12</sub>H<sub>22</sub>O<sub>11</sub>·H<sub>2</sub>O

Chemical Name	Weight-%	Molecular weight	ENCS	ISHL No.	CAS RN
Lactose Hydrate	=<100	360.31	N/A	N/A	64044-51-5

**Note on ISHL No.:** \* in the table means announced chemical substances.

## 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. 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 well-ventilated place at room temperature (preferably cool).  
Keep container tightly closed.

**Safe packaging material**

Polypropylene

**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 ( JIS T 8151 )

**Hand protection**

chemical protective gloves ( JIS T 8116 )

**Eye protection**

protective eyeglasses or chemical safety goggles (JIS T 8147)

**Skin and body protection**

Long-sleeved work clothes

**General hygiene considerations**

Handle in accordance with good industrial hygiene and safety practice.

If this product is classified as "Chemical Substances Hazardous to Skin, etc.", use appropriate protective equipment to them.

**Section 9: PHYSICAL AND CHEMICAL PROPERTIES****Form****Color**

white

**Appearance**

crystals , powder or glannulated 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**

water : freely soluble . Ethanol : 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>	Stable under recommended storage conditions.
<b>Hazardous reactions</b>	None under normal processing
<b>Conditions to avoid</b>	Extremes of temperature and direct sunlight
<b>Incompatible materials</b>	Strong oxidizing agents
<b>Hazardous decomposition products</b>	Carbon monoxide (CO), Carbon dioxide (CO <sub>2</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 data 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>	

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

### 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 (2023.4.1-)	Not applicable
Export Trade Control Order	Not applicable
Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices	Japanese Pharmacopoeia

## Section 16: OTHER INFORMATION

<b>Key literature references and sources for data etc.</b>	NITE: National Institute of Technology and Evaluation (JAPAN) ://www.chem-info.nite.go.jp/chem/chrip/chrip_search/systemTop 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
<b>Record of SDS revisions</b>	The following contents were revised. Product and company Identification. Composition/information on ingredients. Handling and storage. Exposure controls/personal protection. Ecological information. Regulatory information.

### 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 Z 7252:2019. \*JIS: Japanese Industrial Standards

**End of Safety Data Sheet**