

SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH)

Revision Date 06-Mar-2019

Version 1

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Product Name Lactose Hydrate
Product Code 121-06685,129-06681
CAS No. 64044-51-5
Pure substance/mixture Substance

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceuticals raw materials.
Uses advised against No information available

1.3. Details of the supplier of the safety data sheet**Manufacturer**

FUJIFILM Wako Pure Chemical Corporation
1-2 Doshomachi 3-Chome
Chuo-ku, Osaka 540-8605, Japan
Phone: +81 (0)6-6203-3741
Fax: +81 (0)6-6203-4640

Supplier

FUJIFILM Wako Chemicals GmbH
Fuggerstrasse 12, D-41468 Neuss, Germany
Phone: +49 (0)2131-311 158 Fax: +49 (0)2131-311 100
FUJIFILM Wako Chemicals USA, Inc.
1600 Bellwood Road, Richmond, VA 23237-1326, U.S.A.
Phone: +1 (0)804-271-7677 Fax: +1 (0)804-271-7791

For further information, please contact us.

1.4. Emergency telephone number

As above or toxicological information center

Emergency telephone +81-6-6203-3741

Announcement of company name change Company name has changed since April 1, 2018. Former name was "Wako Pure Chemical Industries, Ltd."

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture**

Classification according to Regulation (EC) No. 1272/2008 [CLP]

This substance/mixture is not classified as hazardous according to Regulation (EC) 1272/2008 [CLP].

2.2. Label elements

This product does not need to be labelled according to Regulation (EC) No. 1272/2008 [CLP]

Pictograms

Signal word none

2.3. Other hazards

General Hazards No information available

SECTION 3: Composition/information on ingredients

Chemical Name	EC No	CAS No.	Index No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Lactose Hydrate	N/A	64044-51-5	N/A	=<100	Not classified

3.3 Additional information

Impurities and/or Additives : Not applicable

SECTION 4: First aid measures

4.1. Description of 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 while removing all contaminated clothes and shoes.
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.
Symptoms	No information available.
Note to physicians	Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing media	Water spray, carbon dioxide (CO ₂), dry chemical, alcohol resistant foam.
Unsuitable Extinguishing media	No information available

5.2. Special hazards arising from the substance or mixture Thermal decomposition can lead to release of irritating and toxic gases and vapors.

5.3. Advice for firefighters

Special protective equipment for fire-fighters	Wear self-contained breathing apparatus and protective suit. Use personal protective equipment as required.
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5.4. Additional information No information available

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For emergency responders

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.
Use personal protection recommended in Section 8.

6.2. Environmental precautions

To be careful not discharged to the environment without being properly handled waste water contaminated.
See Section 12 for additional ecological information.

6.3. Methods and material for containment and cleaning up

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

Methods for cleaning up	Take up mechanically, placing in appropriate containers for disposal.
6.4. Reference to other sections	See Section 12: Ecological Information, Section 13 : Disposal considerations

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Protective measures	Ensure adequate ventilation, especially in confined areas. Avoid contact with strong oxidizing agents. Handle in accordance with good industrial hygiene and safety practice.
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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	Keep container tightly closed.
Packaging materials	Glass. Polyethylene.

7.3. Specific end use(s)

Risk Management Methods (RMM)	No information available.
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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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

Engineering controls	Ensure adequate ventilation, especially in confined areas.
Personal protective equipment	
Eye/face protection	Tight sealing safety goggles.
Skin and body protection	Suitable protective clothing.
Respiratory protection	Dust mask.
Environmental exposure controls	No information available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Color	white
Appearance	crystals powder or granulated powder
Odor	No data available
pH	

Melting point / melting range	No data available
Boiling point/boiling range	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limits in Air	
Upper	No data available
Lower	No data available
Vapor pressure	No data available
Vapor density	No data available
Specific Gravity / Density	No data available
Solubility(ies)	water : freely soluble . Ethanol : practically insoluble,or insoluble .
Partition Coefficient (n-octanol/water)	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available

SECTION 10: Stability and reactivity

10.1. Reactivity	
Reactivity	No data available
10.2. Chemical stability	
Stable under recommended storage conditions.	
<u>Explosion data</u>	
Sensitivity to Mechanical Impact	none.
Sensitivity to Static Discharge	none.
10.3. Possibility of hazardous reactions	None under normal processing.
10.4. Conditions to avoid	Extremes of temperature and direct sunlight.
10.5. Incompatible materials	Strong oxidizing agents.
10.6. Hazardous decomposition products	Carbon monoxide (CO). Carbon dioxide (CO ₂).

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	No information available
Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
Respiratory or skin sensitization	No information available
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	No information available
STOT - single exposure	No information available
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.
CMR Effects	No information available

he best of our knowledge, chemical, physical and toxicological properties have not been fully investigated.

SECTION 12: Ecological information

12.1. Toxicity	No information available
12.2. Persistence and degradability	No information available.
12.3. Bioaccumulative potential	No information available.
12.4. Mobility in soil	No information available.
12.5. Results of PBT and vPvB assessment	No information available
12.6. Other adverse effects	No information available

he best of our knowledge, chemical, physical and toxicological properties have not been fully investigated.

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Method of disposing waste from residues / unused products Disposal should be in accordance with applicable regional, national and local laws and regulations.

Precautionary including method of disposing contaminated packaging Improper disposal or reuse of this container may be dangerous and illegal.

SECTION 14: Transport information

IMDG Not regulated

14.1 UN/ID No -

14.2 Proper shipping name Not regulated

14.3 Hazard class Not regulated

14.4 Packing group Not regulated

14.5 Marine pollutant Not applicable

14.6 Special provisions Not regulated

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available

IATA Not regulated

14.1 UN/ID No -

14.2 Proper shipping name Not regulated

14.3 Hazard class Not regulated

14.4 Packing group Not regulated

14.5 Marine pollutant Not applicable

14.6 Special provisions Not regulated

ADR/RID Not regulated

14.1 UN/ID No -

14.2 Proper shipping name Not regulated

14.3 Hazard class Not regulated

14.4 Packing group Not regulated

14.5 Marine pollutant Not applicable

14.6 Special provisions Not regulated

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Water hazard class (WGK) No information available

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

International Inventories

TSCA -

EINECS/ELINCS -

DSL -

NDSL -

ENCS -

15.2. Chemical safety assessment

No information available

SECTION 16: Other information

Revision Date

06-Mar-2019

Key or legend to abbreviations and acronyms used in the safety data sheet

No information available

Disclaimer

The information provided in this Material 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, use, processing, storage, transportation, disposal and release 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.

Product information

You might get a product which indicates a former company name, during the period of transition.

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

End of Safety Data Sheet