

SAFETY DATA SHEET

According to JIS Z 7253:2019
Revision date 08-Aug-2024
Revision Number 2.05

Section 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name	Polysorbate20
Product Code	168-22792

Supplier FUJIFILM Wako Pure Chemical Corporation
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Recommended uses Japanese Pharmaceutical Excipients

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

Serious eye damage/eye irritation

Category 2B

Pictograms

Signal word

Warning

Hazard statements

H320 - Causes eye irritation

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 Substance

Formula C58H114O26

Chemical Name	Weight-%	Molecular weight	ENCS	ISHL No.	CAS RN
Poly(oxyethylene)sorbita n monolaurate	=<100	1227.72	(8)-55	*	9005-64-5

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

Carbon dioxide (CO₂), 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

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

Flammable. Avoid contact with high temperature objects, spark, and 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

Use personal protective equipment as required. Avoid contact with skin, eyes or clothing. Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity)

Storage

Safe storage conditions

Storage conditions

Keep container protect from light tightly closed. Store in a cool (2-10 °C) place.

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

Protective mask

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

Slight yellow - yellow

Appearance

liquid

Odor

Slight peculiar odor

Melting point/freezing point

no data available

Boiling point, initial boiling point and boiling range

>100 °C

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

321 °C

Auto-ignition temperature:

no data available

Decomposition temperature:

no data available

pH

4.0 - 7.0(1.0g/20mL(water))

Viscosity (coefficient of viscosity)

no data available

Dynamic viscosity

350 - 550 mm²/s

Solubilities

water , methanol or Ethanol miscible with . Diethyl ether : slightly soluble .

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

no data available

Vapour pressure

<1.4kPa

Specific Gravity / Relative density

1.090 - 1.130

Vapour density

no data available

Particle characteristics

no data available

Section 10: STABILITY AND REACTIVITY**Stability**

Reactivity no data available
Chemical stability May be altered by light.

Hazardous reactions

None under normal processing

Conditions to avoid

Extremes of temperature and direct sunlight, Heat, flames and sparks, static electricity, spark

Incompatible materials

Strong oxidizing agents

Hazardous decomposition products

Carbon monoxide (CO), Carbon dioxide (CO₂)

Section 11: TOXICOLOGICAL INFORMATION**Acute toxicity**

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Poly(oxyethylene)sorbitan monolaurate	37000 mg/kg (Rat) 36700 µL/kg (Rat)	N/A	> 5.1 mg/L (Rat) 4 h

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 data 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

Japanese regulations

Fire Service Act	Not applicable
Poisonous and Deleterious Substances Control Law	Not applicable
Industrial Safety and Health Act	Not applicable
Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc	Priority Assessment Chemical Substances (Law Article 2, Para.5)
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

Section 16: OTHER INFORMATION

Key literature references and sources for data etc.	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
Record of SDS revisions	The following contents were revised. Product and company Identification.

Composition/information on ingredients. Exposure controls/personal protection.
Toxicological information. 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