

SAFETY DATA SHEET

According to JIS Z 7253:2019
Revision date 15-Feb-2023
Revision Number 2.03

Section 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name	Pitavastatin Calcium
Product Code	163-24861, 169-24863

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

Acute toxicity - Oral

Reproductive Toxicity

Category 3

Category 2

Pictograms



Signal word

Danger

Hazard statements

H301 - Toxic if swallowed

H361 - Suspected of damaging fertility or the unborn child

Precautionary statements-(Prevention)

- Obtain special instructions before use
- Do not handle until all safety precautions have been read and understood
- Use personal protective equipment as required
- Wash face, hands and any exposed skin thoroughly after handling
- Do not eat, drink or smoke when using this product

Precautionary statements-(Response)

- IF exposed or concerned: Get medical advice/attention
- IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
- Rinse mouth

Precautionary statements-(Storage)

- Store locked up

Precautionary statements-(Disposal)

- Dispose of contents/container to an approved waste disposal plant

Others**Other hazards** Not available**Section 3: COMPOSITION/INFORMATION ON INGREDIENTS****Single Substance or Mixture** Substance**Formula** C₅₀H₄₆CaF₂N₂O₈

Chemical Name	Weight-%	Molecular weight	ENCS	ISHL No.	CAS RN
Pitavastatin Calcium	98.0	880.98	N/A	8-(1)-2724	147526-32-7

Note on ISHL No.: * in the table means announced chemical substances.**Impurities and/or Additives:** Not applicable**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 (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

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

Keep container protect from light, store in well-ventilated place at room temperature (preferably cool). Keep container tightly closed.

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 - slightly yellow

Appearance

crystalline powder - 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	dil. hydrochloric acid : soluble . water : Very slightly soluble .
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	May be altered by light.
Hazardous reactions	None under normal processing
Conditions to avoid	Extremes of temperature and direct sunlight, Moisture
Incompatible materials	Strong oxidizing agents
Hazardous decomposition products	Carbon monoxide (CO), Carbon dioxide (CO ₂), Nitrogen oxides (NO _x), Halides

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

UN number	UN2811
Proper shipping name:	Toxic solid, organic, n.o.s. (Pitavastatin Calcium)
UN classification	6.1
Subsidiary hazard class	
Packing group	III
Marine pollutant	Not applicable

IMDG

UN number	UN2811
Proper shipping name:	Toxic solid, organic, n.o.s. (Pitavastatin Calcium)
UN classification	6.1
Subsidiary hazard class	
Packing group	III
Marine pollutant (Sea)	Not applicable
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available

IATA

UN number	UN2811
Proper shipping name:	Toxic solid, organic, n.o.s. (Pitavastatin Calcium)
UN classification	6.1
Subsidiary hazard class	
Packing group	III
Environmentally Hazardous Substance	Not applicable

Section 15: REGULATORY INFORMATION

International Inventories

EINECS/ELINCS	-
TSCA	-

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	Toxic Substances - Poison (Ordinance Art.3, Ministry of Transportation Ordinance Regarding Transport by Ship and Storage, Attached Table 1)
Civil Aeronautics Law	Toxic and Infectious Substances (Ordinance Art.194, MITL Notification for Air Transportation of Explosives etc., Attached Table 1)
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