

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Chemical type : Substance
 TradeName : Lubripharm® SSF NF/EP/JP (Sodium Stearyl Fumarate)
 Product Code(s) : 550-1100

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

1.2.1. Relevant identified uses

Use of the substance/preparation : Lubricant for pharmaceutical formulation

1.3. Details of the supplier of the safety data sheet

SPI Pharma Inc.
 Rockwood Office Park
 503 Carr Road
 Wilmington, Delaware 19809
 (302) 360-7200

1.4. Emergency telephone number

Emergency number : Chemtrec (800) 424-9300; Chemtrec (Outside USA) +1 703-527-3887 (24 hours; 7 days/week)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Not classified

2.1.2. Classification according to Directive 67/548/EEC or 1999/45/EC

Not classified

2.1.3. Adverse physicochemical, human health and environmental effects

No reliable data available.

2.2. Label elements

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

No labelling applicable

2.2.2. Labelling according to Directive 67/548/EEC or 1999/45/EC

No labelling applicable

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS)

No data available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	GHS classification
Sodium stearyl fumarate	(CAS No.) 4070-80-8 (EC no) 223-781-1	> 99	Not classified

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : If respiratory irritation occurs upon inhalation, remove to fresh air. Seek medical attention if symptoms develop or persist.
 First-aid measures after skin contact : After contact with skin, wash immediately with water and soap. If skin irritation persists, take medical advice.
 First-aid measures after eye contact : Immediately rinse with plenty of water. If eye irritation persists: Get medical advice/attention.
 First-aid measures after ingestion : Do not induce vomiting. If the quantity swallowed is significant : Seek medical advice.

Lubripharm® SSF NF/EP/JP (Sodium Stearyl Fumarate)

Safety Data Sheet

According to the federal final rule of hazard communication revised on 2012 (HazCom 2012) and Regulation (EU) 2015/830

4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/injuries after inhalation : Dust from this product may cause respiratory irritation.
Symptoms/injuries after skin contact : Dust from this product may cause skin irritation. May cause skin irritation.
Symptoms/injuries after eye contact : Dust from this product may cause eyes irritation. May cause irritation to the eyes.
Symptoms/injuries after ingestion : Ingestion of small amounts would not be expected to produce toxicity. Ingestion of large amounts may produce gastrointestinal disturbances.

4.3. Indication of any immediate medical attention and special treatment needed

No reliable data available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: : carbon dioxide (CO₂), dry chemical powder, foam. Water fog.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Product is a non-flammable white powder. Material will burn at high temperatures.
Explosion hazard : Accumulation of airborne dusts may present an explosion hazard in the presence of an ignition source.
Reactivity : Combustion generates : Carbon dioxide (CO₂). Carbon monoxide. low molecular weight hydrocarbons.

5.3. Advice for firefighters

Protective equipment for firefighters : Extra personal protection: complete protective clothing including self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

No reliable data available.

6.1.2. For emergency responders

Protective equipment : Wear suitable protective clothing, gloves and eye/face protection. Refer to section 8.

6.2. Environmental precautions

Do not discharge into drains or the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : If sweeping of a contaminated area is necessary, use a dust suppressant agent. Sweep up or vacuum up the product. Use of a moist absorbent is recommended. Avoid raising powdered materials into airborne dust. Do not empty into drains or the aquatic environment. Eliminate all sources of ignition, avoid sparks, flames and do not smoke in risk area.

6.4. Reference to other sections

No reliable data available.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : avoid breathing dust. Avoid contact with skin and eyes. Avoid raising powdered materials into airborne dust. Use only non-sparking tools. Wash hands thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Storage condition(s) : Keep container tightly closed. Store at room temperature.

7.3. Specific end use(s)

No reliable data available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Lubripharm® SSF NF/EP/JP (Sodium Stearyl Fumarate) (4070-80-8)

Italy - Portugal - USA ACGIH

ACGIH TWA (mg/m³)

10 mg/m³ (inhalable particles, recommended) (related to Particulates (insoluble or poorly soluble) not otherwise specified (PNOS))

8.2. Exposure controls

Appropriate engineering controls : Exposures should be minimized in accordance with good industrial hygiene practices. Provide adequate ventilation to minimize dust concentrations.

Lubripharm® SSF NF/EP/JP (Sodium Stearyl Fumarate)

Safety Data Sheet

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Personal protective equipment : Safety glasses. Gloves. Protective clothing.



Materials for protective clothing : long sleeved protective clothing.

Hand protection : protective gloves.

Eye protection : safety glasses with side-shields.

Respiratory protection : In case of insufficient ventilation, wear suitable respiratory equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: fine powder.
Colour	: white.
Odour	: No data available
Odour threshold	: No data available
pH	: No data available
Melting point	: No data available
Solidification point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relat. evapor. rate comp. to butylacetate	: No data available
Flammability (solid, gas)	: No data available
Explosive limits	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: insoluble in water.
Log Pow	: No data available
Self ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: No data available

9.2. Other information

No reliable data available.

SECTION 10: Stability and reactivity

10.1. Reactivity

Combustion generates : Carbon dioxide (CO₂). Carbon monoxide. low molecular weight hydrocarbons.

10.2. Chemical stability

Stable.

10.3. Possibility of hazardous reactions

No reliable data available.

10.4. Conditions to avoid

No reliable data available.

10.5. Incompatible materials

No reliable data available.

10.6. Hazardous decomposition products

carbon dioxide (CO₂). Carbon monoxide. low molecular weight hydrocarbons.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

No reliable data available.

SECTION 12: Ecological information

12.1. Toxicity

No reliable data available.

Lubripharm® SSF NF/EP/JP (Sodium Stearyl Fumarate)

Safety Data Sheet

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12.2. Persistence and degradability

No reliable data available.

12.3. Bioaccumulative potential

No reliable data available.

12.4. Mobility in soil

No reliable data available.

12.5. Results of PBT and vPvB assessment

No reliable data available.

12.6. Other adverse effects

No reliable data available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Disposal must be done according to official regulations.
Waste disposal recommendations : Disposal must be done according to official regulations.
Additional information : Material, if discarded, is not expected to be a characteristic hazardous waste under RCRA.

SECTION 14: Transport information

14.1 Land Transport DOT

DOT Proper Shipping Name: Not dangerous goods
DOT Hazard Class:
UN/NA Number:

14.1. Land Transport (European ADR/RID)

ADR/RID Shipping Name: Not dangerous goods
UN Number:
Hazard Class:

14.3. Air Transport (ICAO/IATA)

ICAO/IATA Shipping Name: Not dangerous goods
Additional Transport: Transport in accordance with local, state and federal regulations

14.7. Transportation in Bulk according to Annex II MARPOL73/78 and the IBC Code

Not Applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

No reliable data available.

15.1.2. National regulations

No reliable data available.

15.2. Chemical safety assessment

No reliable data available.

15.3. International regulations

CANADA

No additional information available

EU-Regulations

No additional information available

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

No additional information available

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

No additional information available

National regulations

No additional information available

Lubripharm® SSF NF/EP/JP (Sodium Stearyl Fumarate)

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SECTION 16: Other information

Abbreviations and acronyms : CAS: Chemical Abstracts Service (division of the American Chemical Society)
CLP: Classification, Labelling and Packaging.
PBT: Persistent, Bioaccumulative and Toxic
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals.
vPvB: very persistent and very bioaccumulative substance.

Other information :

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product. However, we make no warranty of merchantability or any other warranty, expressed or implied, with respect to such information, and we assume no liability resulting from its use. Consumer/User should make their own investigation to determine the suitability of the information for their particular use.