

**LIGAMED MF-2-V-MB, LIGAMED MF-2-V-BI-MB,
LIGAMED MF-2-V E470-MB, LIGAMED MF-2-V
PREMIUM-MB, LIGAMED MF-2-V-MB SSA > 8.5 ,
LIGAMED MF-2-V-MEC-MB, LIGAMED MF-2-V
E470-MB, LIGAMED MF-2-V-BD-MB, LIGAMED
MF-2-V-RS-MB, LIGAMED MF-3-V-MB, LIGAMED
MF-2-K-SG, LIGAMED MF-2-K-SG E470 /
LIGAMED MF-2-V, MF-2-V E470, MF-2-V
PREMIUM, MF-2-V-BI, MF-2-V-MEC, MF-3-K, MF-
3-K-MB, MF-3-V, MF-2-K, MF-2-K-BI, MF-2-K-BI-
MB, MF-2-K-MB, MF-2-K-RS, MF-2-V BD**

Safety Data Sheet

A safety data sheet is not required for this product in accordance with national legal requirements. This document has been created on a voluntary basis following the format of the safety data sheet.
Issue date: 24/11/2021 Revision date: 24/11/2021 Version: 11.00

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

1.1. Product identifier

Product form	: Substance
Trade name	: LIGAMED MF-2-V-MB, LIGAMED MF-2-V-BI-MB, LIGAMED MF-2-V E470-MB, LIGAMED MF-2-V PREMIUM-MB, LIGAMED MF-2-V-MB SSA > 8.5 , LIGAMED MF-2-V-MEC-MB, LIGAMED MF-2-V E470-MB, LIGAMED MF-2-V-BD-MB, LIGAMED MF-2-V-RS-MB, LIGAMED MF-3-V-MB, LIGAMED MF-2-K-SG, LIGAMED MF-2-K-SG E470 / LIGAMED MF-2-V, MF-2-V E470, MF-2-V PREMIUM, MF-2-V-BI, MF-2-V-MEC, MF-3-K, MF-3-K-MB, MF-3-V, MF-2-K, MF-2-K-BI, MF-2-K-BI-MB, MF-2-K-MB, MF-2-K-RS, MF-2-V BD
Chemical name	: Fatty acids, C16-18, magnesium salts
EC-No.	: 209-150-3
CAS-No.	: 557-04-0
Synonyms	: INCI Name: magnesium stearate

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Pharmaceutical industry

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Manufacturer/Supplier

Peter Greven Nederland C.V.
Edisonstraat, 1
NL- 5928PG Venlo
The Netherlands
T +31 (77) 3239323 - F +31 (77) 3239320
info@peter-greven.de

Email competent person

sds@kft.de

1.4. Emergency telephone number

Emergency number : For Hazardous Materials [or Dangerous Goods] Incidents
Spill, Leak, Fire, Exposure, or Accident
Call CHEMTREC Day or Night
Within USA and Canada: 1-800-424-9300
Outside USA and Canada: +1 703-741-5970 (collect calls accepted)

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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

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

No labelling applicable

2.3. Other hazards

Other hazards which do not result in classification : No additional information available.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substances

Comments : Synonyms: magnesium distearate, magnesium soap of a vegetable stearic acid

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Fatty acids, C16-18, magnesium salts	CAS-No.: 557-04-0 EC-No.: 209-150-3	Main constituent	Not classified

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : In case of doubt or persistent symptoms, consult always a physician.
First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. If symptoms persist, call a physician.
First-aid measures after skin contact : Rinse skin with water/shower.
First-aid measures after eye contact : Rinse eyes with water as a precaution.
First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects : No additional information available.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam.
Unsuitable extinguishing media : Strong water jet.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released. Carbon dioxide. Carbon monoxide. Metal oxides.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information : Do not allow run-off from fire fighting to enter drains or water courses. Dispose of in accordance with relevant local regulations. Cool closed containers exposed to fire with water spray. Disposal must be done according to official regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Concerning personal protective equipment to use, see section 8.
Emergency procedures : Ventilate spillage area.
Measures in case of dust release : Avoid dust formation. Provide adequate ventilation to minimize dust concentrations. Keep away from sources of ignition.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. Wear personal protective clothing (see chapter 8). For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Prevent entry to sewers and public waters. Avoid sub-soil penetration.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Moisten spilled material with water. Avoid dust formation. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.
Other information : Shovel into suitable and closed container for disposal. Disposal must be done according to official regulations.

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6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Avoid contact with skin and eyes. Keep away from any flames or sparking source. Precautionary measures fire. Avoid dust formation.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep away from heat and direct sunlight. Protect from moisture. Store in a well-ventilated place. Keep cool.

Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

No additional information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

Fatty acids, C16-18, magnesium salts (557-04-0)

United Kingdom - Occupational Exposure Limits

Observe general threshold limit for dust.

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

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8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:

In case of dust production: protective goggles. EN 166

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing. EN ISO 13982. EN ISO 13688

Hand protection:

In case of repeated or prolonged contact wear gloves. EN 374. Nitrile rubber. Butyl rubber. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. EN 143. Particle filter. P1. Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust.

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: white.
Appearance	: Powder.
Odour	: characteristic. weak.
Odour threshold	: Not available
Melting point	: ≈ 140 °C
Freezing point	: Not applicable
Boiling point	: Not available
Flammability (solid, gas)	: Not flammable
Explosive properties	: Product is not explosive. Dust may form explosive mixture in air.
Explosive limits	: Not applicable
Lower explosive limit (LEL)	: ≈ 30 g/m ³ (Lower explosive limit (LEL))

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Upper explosive limit (UEL)	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Viscosity, dynamic	: Not applicable
Solubility	: Water: Insoluble
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: 0.8 (OECD 107 method)
Vapour pressure	: Not available
Vapour pressure at 50 °C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20 °C	: Not applicable
Particle size	: Not available
Particle size distribution	: Not available
Particle shape	: Not available
Particle aspect ratio	: Not available
Particle aggregation state	: Not available
Particle agglomeration state	: Not available
Particle specific surface area	: Not available
Particle dustiness	: Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available.

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Potential dust explosion hazard from airborne release.

10.4. Conditions to avoid

No additional information available.

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10.5. Incompatible materials

Strong oxidizing agent.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Not relevant)

Fatty acids, C16-18, magnesium salts (557-04-0)

Viscosity, kinematic	Not applicable
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11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute)	: Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Based on available data, the classification criteria are not met)

Fatty acids, C16-18, magnesium salts (557-04-0)

NOEC (chronic)	4000 mg/l (90 d)
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12.2. Persistence and degradability

Fatty acids, C16-18, magnesium salts (557-04-0)

Persistence and degradability	Readily biodegradable.
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12.3. Bioaccumulative potential

Fatty acids, C16-18, magnesium salts (557-04-0)	
Partition coefficient n-octanol/water (Log Pow)	0.8 (OECD 107 method)
Bioaccumulative potential	Bioaccumulation unlikely.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Fatty acids, C16-18, magnesium salts (557-04-0)
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	: Disposal must be done according to official regulations. European waste catalogue. Do not dispose of with domestic waste. Do not discharge into drains or the environment.
Product/Packaging disposal recommendations	: Do not re-use empty containers without proper cleaning or reconditioning. Recycle or dispose of in compliance with current legislation.
European List of Waste (LoW) code	: 07 07 99 - wastes not otherwise specified

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

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ADR	IMDG	IATA	ADN	RID
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

Rail transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

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 REACH Annex XVII restrictions

Fatty acids, C16-18, magnesium salts is not on the REACH Candidate List

Fatty acids, C16-18, magnesium salts is not on the REACH Annex XIV List

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Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

Other information, restriction and prohibition regulations

: A safety data sheet is not required for this product in accordance with national legal requirements. This document has been created on a voluntary basis following the format of the safety data sheet.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

General revision.

Indication of changes			
Section	Changed item	Change	Comments
	SDS Regulation reference	Modified	
1	Trade name	Added	

Abbreviations and acronyms:

ADN	Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
BCF	Bioconcentration factor
CAS	Chemical Abstract Service
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
EC50	Median effective concentration
IATA	International Air Transport Association
IMDG	International Maritime Code for Dangerous Goods
LC50	Median lethal concentration
PBT	Persistent Bioaccumulative Toxic

LIGAMED MF-2-V-MB, LIGAMED MF-2-V-BI-MB, LIGAMED MF-2-V E470-MB, LIGAMED MF-2-V PREMIUM-MB, LIGAMED MF-2-V-MB SSA > 8.5 , LIGAMED MF-2-V-MEC-MB, LIGAMED MF-2-V E470-MB, LIGAMED MF-2-V-BD-MB, LIGAMED MF-2-V-RS-MB, LIGAMED MF-3-V-MB, LIGAMED MF-2-K-SG, LIGAMED MF-2-K-SG E470 / LIGAMED MF-2-V, MF-2-V E470, MF-2-V PREMIUM, MF-2-V-BI, MF-2-V-MEC, MF-3-K, MF-3-K-MB, MF-3-V, MF-2-K, MF-2-K-BI, MF-2-K-BI-MB, MF-2-K-MB, MF-2-K-RS, MF-2-V BD

Safety Data Sheet

A safety data sheet is not required for this product in accordance with national legal requirements. This document has been created on a voluntary basis following the format of the safety data sheet.

Abbreviations and acronyms:	
SDS	Safety Data Sheet
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
vPvB	Very Persistent and Very Bioaccumulative
	RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
NOEC	No-Observed Effect Concentration
PNEC	Predicted No-Effect Concentration
DNEL	Derived-No Effect Level
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
DMEL	Derived Minimal Effect level
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
OECD	Organisation for Economic Co-operation and Development
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
STP	Sewage treatment plant
TLM	Median Tolerance Limit

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KFT SDS EU 00

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.