










Cover Sheet for BioOptimal MF-SL Safety Data Sheet

This *Safety Data Sheet* for the United States (OSHA HCS¹) and the European Union (EU CLP²) covers BioOptimal MF-SL.

Hazard identification

Class	OSHA HCS ¹ and EU CLP ² Classifications			Information for EU CLP ²
	Category	Pictogram	Signal word	H code
20% Ethanol used as preservation agent of BioOptimal MF-SL				
Flammable liquids	3		Danger	H226
Serious eye damage/irritation	2			H319
Carcinogenicity	1			H350
Reproductive toxicity	1			H360
Specific target organ toxicity single exposure	3 (Respiratory tract irritation)			H335
Specific target organ toxicity single exposure	3 (Narcotic effects)			H336
Specific target organ toxicity repeated or prolonged exposure	1			H372

Hazard statements

H code	Hazard statement
H226	Flammable liquid and vapor
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H336	May cause drowsiness or dizziness
H350	May cause cancer
H360	May damage fertility or the unborn child
H372	Causes damage to liver through prolonged or repeated exposure

Precautionary statements for BioOptimal MF-SL for EU CLP²

P201: Obtain special instructions before use.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P314: Get medical advice/attention if you feel unwell.
P337+P313: If eye irritation persists: Get medical advice/attention.

¹OSHA HCS: 29 CFR Part 1910, Federal Register, Vol. 77, No. 58, March 26, 2012

²EU CLP: Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008

Safety Data Sheet

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

1.1. Product Identifier

Product/chemical name: BioOptimal MF-SL

1.2. Relevant uses of product: Hollow fiber membrane for manufacturing of medical products

1.3. Contact information of Manufacturer/Supplier:

Name of manufacturer:

Asahi Kasei Medical Co., Ltd.
Bioprocess Division
1-1-2 Yurakucho, Chiyoda-ku, Tokyo 100-0006 JAPAN
Tel: +81-3-6699-3782; Fax: +81-3-6699-3784
Email address: info.jp@ak-bio.com

Name of supplier (importer) in the EU:

N.V. Asahi Kasei Bioprocess Europe S.A.
Rue Colonel Bourg, 122, 1140 Brussels, Belgium
Tel: +32-2-526-0500; Fax: +32-2-526-0510
Email address: info.eu@ak-bio.com

Name of supplier (importer) in the US:

Asahi Kasei Bioprocess America, Inc.
1855 Elmdale Avenue, Glenview, IL 60026 USA
Tel: +1-847-556-9700; Fax: +1-847-556-9701
Email address: info.us@ak-bio.com

1.4. Emergency telephone number

In case of emergency, call the local poison control center.

Section 2: Hazard identification

Hazard identification is described based on 20 % ethanol used as preservation agent of this product.

2.1. Classification of the substance or mixture

Classification according to OSHA HCS:

Physical Hazards

Flammable liquids: Category 3

Health Hazards

Serious eye damage/eye irritation: Category 2
Carcinogenicity: Category 1
Reproductive toxicity: Category 1
Specific target organ toxicity single exposure: Category 3 (Respiratory tract irritation, Narcotic effects)
Specific target organ toxicity repeated or prolonged exposure: Category 1

Environmental Hazards Not classified

Other Hazards No information

Classification according to EU CLP:

Flam. Liq. 3: H226
Eye Irrit. 2: H319
Carc. 1A: H350
Repr. 1A: H360
STOT SE 3: H335
STOT SE 3: H336
STOT RE 1: H372

2.2. Label elements:

In accordance with OSHA HCS and EU CLP:

Pictogram(s)

Signal word: Danger

Hazard statements:

Flammable liquid and vapor (H226)
Causes serious eye irritation (H319)
May cause respiratory irritation (H335)
May cause drowsiness or dizziness (H336)
May cause cancer (H350)
May damage fertility or the unborn child (H360)
Causes damage to liver through prolonged or repeated exposure (H372)

Precautionary statements:**Prevention**

Obtain special instructions before use. (P201)
Do not handle until all safety precautions have been read and understood. (P202)
Keep away from heat/sparks/open flames/hot surfaces. - No smoking. (P210)
Keep container tightly closed. (P233)
Ground/bond container and receiving equipment. (P240)
Use explosion-proof electrical/ventilating/ lighting/equipment. (P241)
Use only non-sparking tools. (P242)
Take precautionary measures against static discharge. (P243)
Do not breathe dust/fume/gas/mist/ vapors/spray. (P260)
Wash hands thoroughly after handling. (P264)
Do not eat, drink or smoke when using this product. (P270)
Use only outdoors or in a well-ventilated area. (P271)
Wear protective gloves/protective clothing/eye protection/face protection. (P280)

Response

IF ON SKIN (OR HAIR): Take off immediately all contaminated clothing. Rinse skin with water/shower. (P302+P361+P353)

IF INHALED: Remove person to fresh air and keep comfortable for breathing. (P304+P340)

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical advice/attention if you feel unwell. (P305+P351+P338+P314)

IF EYE IRRITATION PERSISTS: Get medical advice/attention. (P337+P313)

IN CASE OF FIRE: Use water mist, dry chemical powder, fire foam or carbon dioxide to extinguish. (P370+P380)

Storage

Store in a well-ventilated place. (P403) Keep container tightly closed. (P233)
Store locked up. (P405)

Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations. (P501)

2.3. Other hazards:

In accordance with OSHA HCS: No information

In accordance with EU CLP: The substance does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

Section 3: Composition/information on ingredients

3.1. Mixtures

Product/chemical name: BioOptimal MF-SL

Materials:

Hollow Fiber Membrane: Polysulfone
Housing: Polysulfone
Sealant: Epoxy resin
Preservation agent: 20 % ethanol

Information on ingredients:

Chemical name	Content (wt %)	CAS No.	EC No.
Ethanol	20	64-17-5	200-578-6
Water	80	7732-18-5	231-791-2

Classification of ingredients contributing to EU CLP hazards classifications*:

Flam. Liq., 3, H226; Eye Irrit., 2, H319; Carc., 1A, H350; Repr., 1A, H360; STOT SE, 3, H335; STOT SE 3, H336; STOT RE, 1, H372

*Full text of hazard statements is given in Section 16 of this *Safety Data Sheet*.

Section 4: First-aid measures

4.1. Description of first aid measures

IF INHALED: If you feel unwell, get medical advice/ attention immediately and at rest.

If symptoms continue, call a doctor/physician.

IF ON SKIN: Rinse with plenty of water.

If symptoms continue, call a doctor/physician.

IF IN EYES: Immediately rinse cautiously with water for 15 - 20 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If symptoms continue, call a doctor/physician.

IF SWALLOWED: Rinse mouth. Immediately get medical advice/attention.

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

Causes eye irritation

May cause respiratory irritation

May cause drowsiness or dizziness

May cause cancer

May damage fertility or the unborn child

Causes damage to liver through prolonged or repeated exposure

May causes damage to central nervous system through prolonged or repeated exposure

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

No information

Section 5: Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing media: Water mist, dry chemical powder, fire foam or carbon dioxide

Unsuitable extinguishing media: Applying direct water may be dangerous because fire may expand to surroundings

5.2. Specific hazards arising from the substance or mixture

In case of fire, toxic decomposition products may be generated.

5.3. Advice for firefighters

Cut off any ignition sources and extinguish with an appropriate agent.

Cool the surrounding tank and the buildings with direct water jet to avoid risk of fire spreading.

Take action from windward.

Keep out except responsible personnel.

Move container to a safe area if it can be done without risk.

Section 6: Accidental release measures

6.1. Personal precautions, protective equipment, and emergency procedures

For non-emergency personnel:

Wear suitable protective equipment (see Section 8) e.g., safety gloves, protective mask and/or protective glasses to prevent exposure.

For emergency responders:

Keep out except responsible personnel.

Wear suitable protective equipment described in "Section 8: Exposure controls/ personal protection"

6.2. Environmental precautions

Avoid release into the environment because product may cause local effects.

6.3. Methods and materials for containment and cleaning up

Stop leak if you can do it without risk.

In case of small amounts, wipe off spilled material with waste or wiping cloth and collect it in an adequate waste container.

If case of large amounts, prevent leakage and enclose by embankment.

Do not eat or drink near handling and storage locations.

ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area).

Prevent to flowing into drains, sewers, basements or closed areas.

6.4. Reference to other sections

Refer to "SECTION 8: Exposure controls/personal protection" and "SECTION 13: Disposal considerations" as appropriate.

Section 7: Handling and storage

7.1. Precautions for safe handling

Protective measures:

Install appropriate equipment and wear suitable protective apparatus described in "Section 8: Exposure controls/ personal protection".

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

Advice on general occupational hygiene:

Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities**Technical measures:**

Install appropriate equipment and wear suitable protective apparatus described in "Section 8: Exposure controls/ personal protection".

Incompatible materials: Oxidizing agents

Conditions for safe storage: Avoid sunlight.

Packing material: Use a sealed container without damage or leakage.

7.3. Specific end use(s)

Hollow fiber membrane for manufacturing of medical products

Section 8: Exposure controls/personal protection

8.1. Control parameters

Acceptable concentration (exposure limit, biological exposure index)
OSHA PEL TWA 1000 ppm, 1900 mg/m³ (Ethanol)
ACGIH TLV-STEL (2014) 1000 ppm (Ethanol)

8.2. Exposure controls**Appropriate engineering controls:**

Shower and eye washer should be available in the work area.
Under high temperature or in case of mist generation, use ventilation.

Personal protective equipment:

Respiratory protection: Wear appropriate protective mask as required.
Hand protection: If hand contact is possible, wear protective gloves.
Eye protection: Wear safety glasses or goggles if necessary.
Skin and body protection: Wear protective clothing and apron if necessary.

8.3. Individual protection measures, such as personal protective equipment:

Respiratory protection: Wear respiratory protective equipment if exposure to vapor/mist/spray is likely. PPE should be to European (EN) or US Standards. Consult manufacturers concerning breakthrough times.
Skin protection: chemical resistant gloves (e.g., butyl or nitrile rubber) and suitable protective clothing (e.g., apron, sleeves and boots).
Eye protection: Wear safety goggles.

8.4. Environmental exposure controls:

Take care to not release product into drains, sewers, and streams or other waterways.

Section 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: Clear liquid
(physical state, form and color)
Odor: Characteristic odor
Odor threshold: No information

pH:	No information
Melting point/freezing point:	No information
Initial boiling point and boiling range:	No information
Flash point:	No information
Evaporation rate:	No information
Flammability (solid, gas):	No information
Upper/lower flammability or explosive limits:	No information
Vapor pressure:	No information
Vapor density:	No information
Relative density:	No information
Solubility (ies):	Miscible in water
Partition coefficient: n-octanol/water:	No information
Auto-ignition temperature:	No information
Decomposition temperature:	No information
Viscosity:	No information

9.2. Other information

No information

Section 10: Stability and reactivity

10.1. Reactivity:

Stable under normal handling condition.

10.2. Chemical stability

Stable under normal handling condition.

10.3. Possibility of hazardous reactions

No hazardous reaction expected under normal handling.

10.4. Conditions to avoid

Avoid sunlight.

10.5. Incompatible materials

Oxidizing agents,

10.6. Hazardous decomposition products

In case of fire, toxic decomposition products may be generated.

Section 11: Toxicological information

11.1 Information on toxicological effects

Information on product:

No information

Information on ethanol:

Acute toxicity (oral):	Rat LD ₅₀ = 6,200 mg/kg
Acute toxicity (dermal):	Rabbit LD ₀ = 20,000 mg/kg
Acute toxicity (inhalation: vapor):	Rat LC ₅₀ = 63,000 ppmV
Skin corrosion/irritation:	Not irritating to rabbit skin.
Serious eye damage/irritation:	Moderately irritating to rabbit eyes.
Carcinogenicity:	IARC classified as Group 1.
Reproductive toxicity:	There are numerous reports that fetal alcohol syndrome which is characterized by growth deficiency, microcephaly,

STOT-single exposure:	characteristic facial characteristics and mental retardation, was observed in the children of alcoholic women. In an inhalation exposure test in humans, stupor, drowsiness and slight paralysis were observed. In addition, suppression of central nervous system was observed in experimental animals.
STOT-repeated exposure:	Long-term consumption of large doses of alcohol causes toxic effects in almost all organ systems. The most affected target organ is the liver; beginning with fatty degeneration, damage can progress via necrosis and fibrotic stages to liver

11.2 Delayed and immediate effects and also chronic effects from short and long term exposure

- Causes eye irritation
- May cause respiratory irritation
- May cause drowsiness or dizziness
- May cause cancer
- May damage fertility or the unborn child
- Causes damage to liver through prolonged or repeated exposure
- May causes damage to central nervous system through prolonged or repeated exposure

11.3 Numerical measures of toxicity

Acute toxicity was estimated based on ingredients of the product by additivity formula.

11.4 Interactive effects

No information

11.5 Whether the chemical is listed in the NTP Report on Carcinogens or has been found to be a potential carcinogen in the IARC Monographs, or by OSHA

IARC: Group 1 (Ethanol)
NTP Report: Not listed
OSHA: Not listed

Section 12: Ecological information

12.1. Toxicity:

Information on product:	No information
Information on ethanol:	
Aquatic acute toxicity:	Fish (Rainbow trout) 96-h LC ₅₀ = 11200 ppm Crustacea (Daphnia magna) = 48-h EC ₅₀ = 5,463 mg/L Algae (Chlorella) = 1,000 mg/L
Aquatic chronic toxicity:	Crustacea (Ceriodaphnia) 10-d NOEC = 9.6 mg/L

12.2. Persistence and degradability:

Information on product:	No information
Information on ethanol:	Rapidly degradable (Degradability by BOD: 89 %)

12.3. Bioaccumulative potential:

Information on product: No information

Information on ethanol: No information

12.4. Mobility in soil:

Information on product: No information

Information on ethanol: No information

12.5. PBT and vPvB in accordance with EU CLP: The product does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

12.6. Other adverse effects:

No information

Section 13: Disposal considerations

13.1. Waste treatment methods

Dispose of waste in accordance with applicable local, regional and international regulations and standards.

When disposing, consult to a licensed contractor or local offices if they deal with the waste. Used container should be recycled after cleaning or dispose of in compliance with related laws and local regulations.

Contents should be removed completely when dispose of empty containers.

Section 14: Transport information

14.1. UN number:

Not applicable

14.2. UN proper shipping name:

Not applicable

14.3. Transport hazard class(es):

Not applicable

14.4. Packing group:

Not applicable

14.5. Environmental hazards:

Not applicable

14.6. Special precautions for user:

When transporting, avoid direct sunlight. Confirm no leakage to containers. When loading, prevent containers from falling, dropping off or damaging. Take preventive measures of collapse.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code

Not applicable

Section 15: Regulatory information

15.1. Safety, health and environmental regulations specific for the product in question

The product and its ingredients are not regulated by specific provisions related to protection of human health or the environment at EU level, e.g. not considered as SVHCs or POPs.

UNITED STATES

OSHA: Hazardous chemical

TSCA inventory: Ethanol is listed on the TSCA Inventory.

TSCA SNUR: Not listed

15.2. Chemical safety assessment: Not conducted

Section 16: Other information

Update history:

Date of issue: December 15, 2015

Date of most recent revision: October 1, 2018; Supersedes Version 1.0 issued December 15, 2015

Sections revised: Content changes were made to Sections 1 and 16.

References:

NITE GHS classification results (2015).

ACGIH, American Conference of Governmental Industrial Hygienists (2014) TLVs and BEIs.

Full text of Hazard statements referred to in Sections 2 and 3:

H226 Flammable liquid and vapor

H319 Causes eye irritation

H350 May cause cancer

H360FD May damage fertility or the unborn child

H335 May cause respiratory irritation

H336 May cause drowsiness or dizziness

H372 Causes damage to liver through prolonged or repeated exposure

Relevant hazard statements of which do not appear elsewhere in this SDS:

H225: Highly flammable liquid and vapor

Abbreviations

PBT: Persistent, Bioaccumulative and Toxic substance

POPs: Persistent Organic Pollutants

STOT: Specific Target Organ Toxicity

SVHC: Substances of Very High Concern

vPvB: Very Persistent and Very Bioaccumulative

[Disclaimer]

This SDS has been prepared based on the best available information however, it may not be sufficient in some cases. It is user's responsibility to modify or update any contents in this SDS regarding information on hazardous properties and/or instruction for safe handling of the product when they become available. Precautionary measures in this SDS are only applicable for normal handling conditions and it is necessary to take appropriate additional measures to ensure safe handling which depend on your specific use conditions or situations