

# SAFETY DATA SHEET

## BioOptimal™

Version 2.0      Revision Date: 25.12.2024      SDS Number: TAQ35068EN-NZ      Date of last issue: -  
Date of first issue: 15.12.2015

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### Section 1: Identification

Product name : BioOptimal™ (Containing 17 wt% Ethanol as preservative)

#### Manufacturer or supplier's details

Company : Asahi Kasei Medical Co., Ltd.  
Bioprocess Division

Address : 1-1-2 Yurakucho  
Chiyoda-ku, Tokyo Japan 100-0006

Telephone : +81-3-6699-3782

Emergency telephone number : +81-3-6699-3782

E-mail address : bioprocessjp-ml@aml.asahi-kasei.co.jp

#### Recommended use of the chemical and restrictions on use

Recommended use : Biocides  
Preservatives for products during storage

Restrictions on use : Not applicable

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### Section 2: Hazard identification

#### GHS Classification

Flammable liquids : Category 3

#### GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H226 Flammable liquid and vapour.

Precautionary statements : **Prevention:**  
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
P233 Keep container tightly closed.

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P241 Use explosion-proof electrical/ ventilating/ lighting equipment.  
P242 Use non-sparking tools.  
P243 Take action to prevent static discharges.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.  
P370 + P378 In case of fire: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide to extinguish.

**Storage:**

P403 + P235 Store in a well-ventilated place. Keep cool.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards which do not result in classification**

Vapours may form explosive mixture with air.

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**Section 3: Composition/information on ingredients**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Ethanol	64-17-5	>= 10 -< 20

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**Section 4: First-aid measures**

If inhaled : If inhaled, remove to fresh air.  
Get medical attention if symptoms occur.

In case of skin contact : Remove contaminated clothing and shoes.

In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention if symptoms occur.  
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : None known.

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Protection of first-aiders : No special precautions are necessary for first aid responders.

Notes to physician : Treat symptomatically and supportively.

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### Section 5: Fire-fighting measures

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : High volume water jet

Specific hazards during fire-fighting : Do not use a solid water stream as it may scatter and spread fire.  
Flash back possible over considerable distance.  
Vapours may form explosive mixtures with air.  
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.  
Use personal protective equipment.

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### Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures : Remove all sources of ignition.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.

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Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Non-sparking tools should be used.  
Soak up with inert absorbent material.  
Suppress (knock down) gases/vapours/mists with a water spray jet.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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### Section 7: Handling and storage

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.  
Use explosion-proof electrical, ventilating and lighting equipment.

Advice on safe handling : Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Non-sparking tools should be used.  
Keep container tightly closed.  
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
Take precautionary measures against static discharges.  
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.

Conditions for safe storage : Keep in properly labelled containers.  
Keep tightly closed.  
Keep in a cool, well-ventilated place.

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Store in accordance with the particular national regulations.  
Keep away from heat and sources of ignition.

Materials to avoid : Do not store with the following product types:  
Self-reactive substances and mixtures  
Organic peroxides  
Oxidizing agents  
Flammable gases  
Pyrophoric liquids  
Pyrophoric solids  
Self-heating substances and mixtures  
Poisonous gases  
Explosives

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### Section 8: Exposure controls/personal protection

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ethanol	64-17-5	WES-TWA	200 ppm 380 mg/m <sup>3</sup>	NZ OEL
	Further information: Ototoxin			
		WES-STEL	800 ppm 1,520 mg/m <sup>3</sup>	NZ OEL
	Further information: Ototoxin			
		STEL	1,000 ppm	ACGIH

**Engineering measures** : Minimize workplace exposure concentrations.  
If sufficient ventilation is unavailable, use with local exhaust ventilation.  
Use explosion-proof electrical, ventilating and lighting equipment.

#### Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Organic vapour type

Hand protection  
Material : Natural Rubber

Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. For special applications,

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we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday. Breakthrough time is not determined for the product. Change gloves often!

- Eye protection : Wear the following personal protective equipment:  
Safety glasses
- Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.  
Wear the following personal protective equipment:  
If assessment demonstrates that there is a risk of explosive atmospheres or flash fires, use flame retardant antistatic protective clothing.  
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

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### Section 9: Physical and chemical properties

- Appearance : liquid
- Colour : clear
- Odour : No data available
- Odour Threshold : No data available
- pH : No data available
- Melting point/freezing point : No data available
- Initial boiling point and boiling range : No data available
- Flash point : 40 °C
- Evaporation rate : No data available
- Flammability (solid, gas) : Not applicable
- Flammability (liquids) : No data available

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Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Auto-ignition temperature : does not ignite

Decomposition temperature : The substance or mixture is not classified self-reactive.

Viscosity  
Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Particle characteristics  
Particle size : Not applicable

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### Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Flammable liquid and vapour.  
Vapours may form explosive mixture with air.  
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.

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products

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### Section 11: Toxicological information

Exposure routes : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

##### Ethanol:

Acute oral toxicity : LD50 (Rat): 10,470 mg/kg  
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat, male): 116.9 mg/l  
Exposure time: 4 h  
Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rabbit): > 15,800 mg/kg

#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### Ethanol:

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

#### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

##### Ethanol:

Species : Rabbit  
Result : Irritation to eyes, reversing within 21 days  
Method : OECD Test Guideline 405

#### Respiratory or skin sensitisation

##### Skin sensitisation

Not classified based on available information.



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### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### **Ethanol:**

Test Type : Mouse ear swelling test (MEST)  
Exposure routes : Skin contact  
Species : Mouse  
Result : negative

### Chronic toxicity

#### **Germ cell mutagenicity**

Not classified based on available information.

#### Components:

##### **Ethanol:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Rat  
Application Route: Ingestion  
Result: negative

### Carcinogenicity

Not classified based on available information.

#### **Reproductive toxicity**

Not classified based on available information.

#### Components:

##### **Ethanol:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Mouse  
Application Route: Ingestion  
Result: negative

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### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Repeated dose toxicity

#### Components:

##### Ethanol:

Species : Rat  
NOAEL : 1,730 mg/kg  
LOAEL : 3,200 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

### Aspiration toxicity

Not classified based on available information.

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## Section 12: Ecological information

### Ecotoxicity

#### Components:

##### Ethanol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 14,200 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 5,012 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l  
Exposure time: 72 h

EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l  
Exposure time: 72 h

Toxicity to fish (Chronic toxicity) : NOEC (Oryzias latipes (Japanese medaka)):  $\geq$  79 mg/l  
Exposure time: 100 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 9.6 mg/l  
Exposure time: 9 d

Toxicity to microorganisms : EC50 (Protozoa): 5,800 mg/l  
Exposure time: 4 h

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### Persistence and degradability

#### Components:

##### Ethanol:

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 84 %  
Exposure time: 20 d

### Bioaccumulative potential

#### Components:

##### Ethanol:

Partition coefficient: n-octanol/water : log Pow: -0.35

### Mobility in soil

No data available

### Other adverse effects

No data available

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## Section 13: Disposal considerations

### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Empty containers retain residue and can be dangerous.  
Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death.  
If not otherwise specified: Dispose of as unused product.

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## Section 14: Transport information

### International Regulations

#### UNRTDG

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable

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Labels : Not applicable  
Environmentally hazardous : no

### IATA-DGR

UN/ID No. : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction (passenger aircraft) : Not applicable

### IMDG-Code

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
EmS Code : Not applicable  
Marine pollutant : Not applicable

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### National Regulations

#### NZS 5433

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Hazchem Code : Not applicable

### Special precautions for user

Not applicable

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## Section 15: Regulatory information

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

#### HSNO Approval Number

HSR002621 N.O.S. Flammable Group Standard

Tolerable Exposure Limits (TEL)

Not applicable

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Environmental Exposure Limits (EEL)

Not applicable

### HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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### Section 16: Other information

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#### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : dd.mm.yyyy

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / STEL : Short-term exposure limit  
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average  
NZ OEL / WES-STEEL : Workplace Exposure Standard - Short-Term Exposure Limit

AllC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumu-

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lative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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