

SAFETY DATA SHEET

BioOptimal™

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

Section 1: Identification

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

Recommended use of the chemical and restrictions on use

Recommended use : Biocides
Preservatives for products during storage

Restrictions on use : Not applicable

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

Section 2: Hazard identification

Classification of the substance or mixture

Flammable liquids : Category 3

GHS Label elements, including precautionary statements

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.

SAFETY DATA SHEET

BioOptimal™

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

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/ hearing 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.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

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

Section 4: First-aid measures

Description of necessary 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

Risks : None known.

SAFETY DATA SHEET

BioOptimal™

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

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

Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : High volume water jet

Special hazards arising from the substance or mixture

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

Special protective actions for fire-fighters

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

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.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

SAFETY DATA SHEET

BioOptimal™

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

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

Environmental precautions

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

Methods and materials for containment and cleaning up

Methods for 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.

Section 7: Handling and storage

Precautions for safe handling

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.

SAFETY DATA SHEET

BioOptimal™

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

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, including any incompatibilities

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

Section 8: Exposure controls/personal protection

Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ethanol	64-17-5	PEL (long term)	1,000 ppm 1,880 mg/m ³	SG OEL
		STEL	1,000 ppm	ACGIH

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

Individual protection measures, such as personal protective equipment (PPE)

SAFETY DATA SHEET

BioOptimal™

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

- Eye/face protection : Wear the following personal protective equipment:
Safety glasses
- Skin 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).
- 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, 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!

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

SAFETY DATA SHEET

BioOptimal™

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

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

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

Section 10: Stability and reactivity

SAFETY DATA SHEET

BioOptimal™

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

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 products : No hazardous decomposition products are known.

Section 11: Toxicological information

Information on likely routes of exposure : 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.

SAFETY DATA SHEET

BioOptimal™

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

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.

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

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.

SAFETY DATA SHEET

BioOptimal™

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

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

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.

Section 12: Ecological information

Toxicity

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

SAFETY DATA SHEET

BioOptimal™

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

Toxicity to fish (Chronic toxicity) : NOEC (Oryzias latipes (Japanese medaka)): ≥ 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

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

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.

SAFETY DATA SHEET

BioOptimal™

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

Section 14: Transport information

International Regulations

UNRTDG

UN number : Not applicable
UN proper shipping name : Not applicable
Transport hazard class(es) : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
UN proper shipping name : Not applicable
Transport hazard class(es) : 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
UN proper shipping name : Not applicable
Transport hazard class(es) : 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 IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

Section 15: Regulatory information

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable
Environmental Protection and Management (Hazardous Substances) Regulations

SAFETY DATA SHEET

BioOptimal™

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

Fire Safety (Petroleum and Flammable Materials) Regulations : Ethanol

Section 16: Other information

Revision Date : 25.12.2024

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)
SG OEL : Singapore. Workplace Safety and Health (General Provisions) Regulations - First Schedule Permissible Exposure Limits of Toxic Substances.

ACGIH / STEL : Short-term exposure limit
SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

AIC - 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, Bioaccumulative 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 Tem-

SAFETY DATA SHEET

BioOptimal™

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

perature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - 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.

SG / EN