

Safety Data Sheet

日本

1. Product and company identification

Product name HyClone™ prime expression medium (chemically

defined), 500L

Catalogue Number SH31198.05

Product type Powder.

Original preparation date 7/18/2024

Date of issue/Date of revision 9/10/2025

Date of previous issue 7/18/2024

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

For further manufacturing.

Supplier / Manufacturer

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2. Hazards identification

GHS Classification HAZARDOUS TO THE AQUATIC ENVIRONMENT - ACUTE HAZARD - Category 3

HAZARDOUS TO THE AQUATIC ENVIRONMENT - CHRONIC HAZARD - Category 3

Percentage of the mixture consisting of ingredient(s) of unknown hazards to the aquatic environment:

46.6%

GHS label elements

Signal word No signal word.

Hazard statements Harmful to aquatic life with long lasting effects.

Precautionary statements

General

Prevention Avoid release to the environment.

ResponseNot applicable.StorageNot applicable.

Disposal Dispose of contents and container in accordance with all local, regional, national and international

regulations.

Other hazards which do not

result in classification

May form explosible dust-air mixture if dispersed.

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3. Composition/information on ingredients

Substance/mixture Mixture

Ingredient name	含有量(%)	Identifiers	Official Gazette notice reference number	
			CSCL	ISHL
sodium chloride	15.404 - 15.405	CAS: 7647-14-5	1-236	Not available.
L-serine	<2.55	CAS: 56-45-1	9-1585	Not available.
potassium chloride	<2.4	CAS: 7447-40-7	1-228	(1)-228
L-valine	<1.4	CAS: 72-18-4	9-1604	Not available.

4. First aid measures

Inhalation Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of

inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may

need to be kept under medical surveillance for 48 hours.

Skin contact Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get

medical attention if symptoms occur.

Eye contact Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check

for and remove any contact lenses. Get medical attention if irritation occurs.

Wash out mouth with water. If material has been swallowed and the exposed person is conscious, Ingestion give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical

personnel.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Inhalation Exposure to airborne concentrations above statutory or recommended exposure limits may cause

irritation of the nose, throat and lungs

Skin contact No known significant effects or critical hazards.

Eye contact Exposure to airborne concentrations above statutory or recommended exposure limits may cause

irritation of the eyes.

Ingestion No known significant effects or critical hazards.

Short term exposure

Potential delayed effects Not available.

Over-exposure signs/symptoms

Inhalation Adverse symptoms may include the following:

respiratory tract irritation

coughing

Skin contact No specific data

Eye contact Adverse symptoms may include the following:

irritation

redness

Ingestion No specific data.

Protection of first-aiders No action shall be taken involving any personal risk or without suitable training.

Notes to physician In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed

person may need to be kept under medical surveillance for 48 hours.

Fire-fighting measures 5.

Suitable extinguishing media Use dry chemical powder.

Unsuitable extinguishing media Avoid high pressure media which could cause the formation of a potentially explosible dust-air

Specific hazards arising from

the chemical

May form explosible dust-air mixture if dispersed. This material is harmful to aquatic life with long lasting effects. Fire water contaminated with this material must be contained and prevented from

being discharged to any waterway, sewer or drain.

Special protective actions for

fire-fighters

Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.

Special protective equipment for fire-fighters

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

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Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel No action shall be taken involving any personal risk or without suitable training. Evacuate

surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Shut off all ignition sources. No flares, smoking or flames in hazard

area. Avoid breathing dust. Put on appropriate personal protective equipment.

If specialized clothing is required to deal with the spillage, take note of any information in Section 8 For emergency responders on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways,

soil or air). Water polluting material. May be harmful to the environment if released in large

quantities.

Methods and materials for containment and cleaning up

Small spill Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Vacuum or

sweep up material and place in a designated, labeled waste container. Dispose of via a licensed

Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach Large spill

release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Vacuum or sweep up material and place in a designated, labeled waste container. Avoid creating dusty conditions and prevent wind dispersal. Dispose of via a licensed waste disposal contractor.

7. Handling and storage

Environmental precautions

Handling

Protective measures

Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Avoid release to the environment. Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Prevent dust accumulation. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Electrical equipment and lighting should be protected to appropriate standards to prevent dust coming into contact with hot surfaces, sparks or other ignition sources. Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Empty containers retain product residue and can be hazardous. Do not reuse

Advice on general occupational hygiene

Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

Storage

Conditions for safe storage

Store between the following temperatures: 2 to 8°C (35.6 to 46.4°F). Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Eliminate all ignition sources. Separate from oxidizing materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use

Exposure controls/personal protection

Appropriate engineering controls

Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Use explosionproof ventilation equipment

Occupational exposure limits **Biological exposure indices**

No exposure indices known

Individual protection measures

Respiratory protection

Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Hand protection

Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated

Article Number 31141435 Page: 3/9 **Eye protection** Safety eyewear complying with an approved standard should be used when a risk assessment

indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields. If operating conditions cause high dust concentrations

to be produced, use dust goggles.

Skin protection Personal protective equipment for the body should be selected based on the task being performed

and the risks involved and should be approved by a specialist before handling this product.

Appropriate footwear and any additional skin protection measures should be selected based on the

task being performed and the risks involved and should be approved by a specialist before handling

this product.

9. Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

Physical state
Color
Off-white.
Odor
Not available.
Odor threshold
Ph
5.2 to 7.4
Melting point/freezing point
Boiling point or initial boiling
point and boiling range

Flash point Not applicable.

Evaporation rate Not available.

Flammability Not available.

Lower and upper explosive Not applicable.

(flammable) limits

 Vapor pressure
 Not available.

 Relative vapor density
 Not applicable.

 Relative density
 Not available.

 Solubility in water
 Not available.

 Partition coefficient: n-octanol/ water
 Not applicable.

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Auto-ignition temperature Not applicable.

Decomposition temperature Not available.

Viscosity Dynamic (room temperature): Not available.

Kinematic (room temperature): Not available. Kinematic (40°C (104°F)): Not available.

Particle characteristics

Median particle sizeNot available.SADTNot available.

Viscosity Dynamic (room temperature): Not available.
Kinematic (room temperature): Not available.

Kinematic (40°C (104°F)): Not available.

Flow time (ISO 2431)

Burning rate

Burning time

Not available.

Not available.

10. Stability and reactivity

Reactivity No specific test data related to reactivity available for this product or its ingredients.

Chemical stability The product is stable.

Possibility of hazardous

reactions

Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame).

Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before

transferring material. Prevent dust accumulation.

Incompatible materials Reactive or incompatible with the following materials:

oxidizing materials

Hazardous decomposition

products

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

produced.

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11. Toxicological information

Acute toxicity

L-valine

Product/ingredient name

L-serine Rat - Oral - LD50

Result

14 g/kg Rat - Male - Oral - LD50 potassium chloride

2600 mg/kg

Toxic effects: Gastrointestinal - Hypermotility, diarrhea Gastrointestinal -

Nausea or vomiting

Rat - Oral - LD50 2000 mg/kg

Acute toxicity estimates

Product/ingredient name	Oral (mg/ kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
HyClone™ prime expression medium (chemically defined)	42996.7	175553.8	N/A	N/A	N/A
L-serine	14000	N/A	N/A	N/A	N/A
potassium chloride	2600	N/A	N/A	N/A	N/A
L-valine	2000	N/A	N/A	N/A	N/A

Skin corrosion/irritation

Not available.

Conclusion/Summary [Product] Not available.

Ingredient name Conclusion/Summary May cause skin irritation. L-serine L-valine May cause skin irritation.

Serious eye damage/eye irritation

Not available.

Conclusion/Summary [Product] Not available.

Ingredient name Conclusion/Summary May cause eye irritation. L-serine L-valine May cause eye irritation.

Respiratory corrosion/irritation

Not available.

Conclusion/Summary [Product] Not available.

Respiratory or skin sensitization

Not available.

Skin

Conclusion/Summary [Product] Not available.

Respiratory

Conclusion/Summary [Product] Not available.

Germ cell mutagenicity

Not available.

Conclusion/Summary [Product] Not available.

Carcinogenicity

Not available.

Conclusion/Summary [Product] Not available.

Reproductive toxicity

Article Number 31141435 Page: 5/9 Conclusion/Summary [Product] Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

12. Ecological information

Toxicity

Product/ingredient name

sodium chloride

Result

Acute - LC50 - Fresh water

Fish - Striped bass - Morone saxatilis - Larvae

1000 mg/l [96 hours] Effect: Mortality

Chronic - NOEC - Fresh water Daphnia - Water flea - Daphnia pulex

0.314 g/l [21 days] Effect: Reproduction

Chronic - NOEC - Fresh water

Fish - Eastern mosquitofish - Gambusia holbrooki - Adult

100 mg/l [8 weeks] Effect: Reproduction

Chronic - NOEC - Fresh water

OECD

Aquatic plants - Duckweed - Lemna minor

6 g/l [96 hours] Effect: Growth

Acute - EC50 - Fresh water

Daphnia - Water flea - Daphnia magna

402.6 mg/l [48 hours] Effect: Intoxication

Acute - EC50 - Fresh water

Algae - Green algae - Selenastrum capricornutum

28.85 mg/dm³ [72 hours]
<u>Effect</u>: Population **Acute - EC50**Daphnia

83 mg/l [48 hours] Acute - NOEC

Algae

1000 mg/l [72 hours]

Acute - LC50 - Fresh water

Crustaceans - Water flea - Pseudosida ramosa - Neonate

Age: ≤24 hours 9.68 mg/l [48 hours] Effect: Mortality

Acute - EC50 - Fresh water

ISO

Algae - Green algae - Desmodesmus subspicatus

9.24 g/l [72 hours] Effect: Population

Acute - LC50 - Fresh water Fish - Zebra danio - Danio rerio

509.65 mg/l [96 hours] Effect: Mortality

LC50 Fish

10000 mg/l [96 hours]

Conclusion/Summary [Product] Not available.

Ingredient name

L-serine L-valine

L-valine

I -serine

potassium chloride

Conclusion/Summary

Naturally occurring substance Naturally occurring substance

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Persistence/degradability

Product/ingredient name Result
L-valine 82% [28 days]

Conclusion/Summary [Product] Not available.

Ingredient name Conclusion/Summary

L-serine Not expected to bioaccumulate. Naturally occurring substance L-valine Not expected to bioaccumulate. Naturally occurring substance

Product/ingredient nameAquatic half-lifePhotolysisBiodegradabilityL-valine-Readily

Bioaccumulative potential

Product/ingredient nameLogPowBCFPotentialL-serine-3.070.609LowL-valine-2.260.846Low

Mobility in soil

Soil/Water partition coefficientNot available.MobilityNot available.Hazardous to the ozone layerNot applicable.

Other adverse effects No known significant effects or critical hazards.

13. Disposal considerations

Disposal methods

The generation of waste should be avoided or minimized wherever possible. Disposal of this product,

solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and

runoff and contact with soil, waterways, drains and sewers.

14. Transport information

	UN	IMDG	IATA
UN number	Not available.	Not available.	Not available.
UN proper shipping name	Not available.	Not available.	Not available.
Transport hazard class (es)	Not available.	Not available.	Not available.
Packing group	-	-	-
Environmental hazards	No.	No.	No.
Additional information	-	-	-

Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or

spillage

Transport in bulk according to

Special precautions for user

IMO instruments

Not available.

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15. Regulatory information

Fire Service Law

None of the components are listed.

Fire Service Law - Obstructive Not listed

materials

Industrial Safety and Health Act

Ordinance on the Prevention of the Hazard due to Specified Chemical Substances

None of the components are listed.

Organic solvents poisoning prevention

Not applicable.

Substance(s) requiring labelling

* Any concentration shown as a range is to protect confidentiality.

Chemicals requiring notification

* Any concentration shown as a range is to protect confidentiality.

Chemical substances that cause skin disorders, etc. and other chemical substances that must be handled with impermeable protective equipment etc. based on special chemical regulations. (Article 594-2 Paragraph 1 of Ordinance on ISH)

None of the components are listed.

Carcinogens based on Article 577-2 of the Ordinance on ISH

None of the components are listed.

Mutagen

None of the components are listed.

Corrosive liquid Not listed

ISHL Enforcement Order Appendix 1 - Dangerous

Substances

Harmful Substances Subject to Obtaining Permission for

Manufacturing

Not listed

Not listed

Oxidizing, Inflammable

Harmful Substances,

Prohibited for Manufacturing

Chemical Substances Control Law (CSCL)

None of the components are listed.

Poisonous and Deleterious Substances

None of the components are listed.

Pollutant Release and Transfer Registers (PRTR)

None of the components are listed.

JSOH Carcinogen

Law concerning prevention of

pollution of the ocean

Not listed
Not available.

Road law Not available
List of Specially Controlled Not listed

Industrial Waste

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

Validation date 10 September 2025

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

International lists

National inventory

Japan inventory (CSCL): Not determined.

Japan inventory (ISHL): Not determined.

United States Not determined.

Canada inventory Not determined.

China At least one component is not listed.

16. Other information

History

Date of printing9/10/2025Date of issue/Date of revision9/10/2025Date of previous issue7/18/2024Version0.02

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ATE = Acute Toxicity Estimate

BCF = Bioconcentration Factor

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IATA = International Air Transport Association

IBC = Intermediate Bulk Container

IMDG = International Maritime Dangerous Goods

LogPow = logarithm of the octanol/water partition coefficient

MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by

the Protocol of 1978. ("Marpol" = marine pollution)

N/A = Not available UN = United Nations

Procedure used to derive the classification

Classification Justification

HAZARDOUS TO THE AQUATIC ENVIRONMENT - ACUTE

HAZARD - Category 3

HAZARDOUS TO THE AQUATIC ENVIRONMENT - CHRONIC

Calculation method

Calculation method

HAZARD - Category 3

References Not available.

Indicates information that has changed from previously issued version.

Notice to reader

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