

Safety Data Sheet

日本

1. Product and company identification

Product name ActiPRO™, with Poloxamer-188, without Insulin, without L-Glutamine, 5kg

Catalogue Number SH31037.09

Product type Solid.

Original preparation date 11/6/2025

Date of issue/Date of revision 11/6/2025

Date of previous issue No previous validation

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

For Further Manufacturing or Research Use. Not for Diagnostic or Therapeutic Use.

Supplier / Manufacturer

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2. Hazards identification

GHS Classification

EYE IRRITATION - Category 2A

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:
43.8%

GHS label elements

Hazard pictograms



Signal word

Warning

Hazard statements

Causes serious eye irritation.

Harmful to aquatic life with long lasting effects.

Precautionary statements

General

Wear eye or face protection. Avoid release to the environment. Wash thoroughly after handling.

Prevention

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice or attention.

Storage	Not 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	None known.

3. Composition/information on ingredients

Substance/mixture Mixture

Ingredient name	含有量(%)	Identifiers	Official Gazette notice reference number	
			CSCL	ISHL
sodium chloride	<14.5	CAS: 7647-14-5	1-236	Not available.
succinic acid	<5.95	CAS: 110-15-6	2-846	Not available.
potassium chloride	<3.65	CAS: 7447-40-7	1-228	(1)-228
L-serine	<3.1	CAS: 56-45-1	9-1585	Not available.
ammonium iron(III) citrate	<2.3	CAS: 1185-57-5	2-895	Not available.
L-valine	<2.15	CAS: 72-18-4	9-1604	Not available.
sodium selenite	<0.00015	CAS: 10102-18-8	1-507	Not available.

4. First aid measures

Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. 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. Wash clothing before reuse. Clean shoes thoroughly before reuse.
Eye contact	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.
Ingestion	Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Inhalation	No known significant effects or critical hazards.
Skin contact	No known significant effects or critical hazards.
Eye contact	Causes serious eye irritation.
Ingestion	No known significant effects or critical hazards.

Short term exposure

Potential delayed effects	Not available.
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Over-exposure signs/symptoms

Inhalation	No specific data.
Skin contact	No specific data.
Eye contact	Adverse symptoms may include the following: pain or irritation watering redness
Ingestion	No specific data.

Protection of first-aiders	No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.
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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.

5. Fire-fighting measures

Suitable extinguishing media	Use an extinguishing agent suitable for the surrounding fire.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	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.
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.

6. 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. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
For emergency responders	If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".
Environmental precautions	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. Avoid dust generation. Using a vacuum with HEPA filter will reduce dust dispersal. Place spilled material in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.
Large spill	Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor.

7. Handling and storage

Handling

Protective measures	Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Avoid release to the environment. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
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 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. 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.
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8. Exposure controls/personal protection

Appropriate engineering controls	Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
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Occupational exposure limits

Ingredient name

sodium selenite

Exposure limits

Japan Society for Occupational Health (Japan, 5/2024) [Selenium and compounds (except SeH2 and SeF6)]

OEL-M 8 hours: 0.1 mg/m³ (measured as Se).

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.
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: chemical splash 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	Solid.
Color	White to yellowish.
Odor	Not available.
Odor threshold	Not available.
pH	3 to 4
Melting point/freezing point	Not available.
Boiling point or initial boiling point and boiling range	Not available.
Flash point	Not applicable.
Evaporation rate	Not available.
Flammability	Not available.
Lower and upper explosive (flammable) limits	Not applicable.
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.
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 size	Not available.
SADT	Not available.
Viscosity	Dynamic (room temperature): Not available. Kinematic (room temperature): Not available. Kinematic (40°C (104°F)): Not available.
Flow time (ISO 2431)	Not available.
Burning rate	Not available.
Burning time	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	No specific data.
Incompatible materials	No specific data.

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

11. Toxicological information

Acute toxicity

Product/ingredient name	Result
succinic acid	Rat - Oral - LD50 2260 mg/kg
potassium chloride	Rat - Male - Oral - LD50 2600 mg/kg <u>Toxic effects:</u> Gastrointestinal - Hypermotility, diarrhea Gastrointestinal - Nausea or vomiting
L-serine	Rat - Oral - LD50 14 g/kg
ammonium iron(III) citrate	Rat - Oral - LD50 2001 mg/kg
L-valine	Rat - Oral - LD50 2000 mg/kg
sodium selenite	Rat - Oral - LD50 7 mg/kg <u>Toxic effects:</u> Behavioral - Somnolence (general depressed activity) Lung, Thorax, or Respiration - Dyspnea Gastrointestinal - Hypermotility, diarrhea

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™ ActiPro™	13462.7	116599.3	N/A	N/A	N/A
succinic acid	2260	N/A	N/A	N/A	N/A
potassium chloride	2600	N/A	N/A	N/A	N/A
L-serine	14000	N/A	N/A	N/A	N/A
ammonium iron(III) citrate	2001	N/A	N/A	N/A	N/A
L-valine	2000	N/A	N/A	N/A	N/A
sodium selenite	7	N/A	N/A	N/A	N/A

Skin corrosion/irritation

Not available.

Conclusion/Summary [Product] Not available.

Ingredient name

L-serine
L-valine

Conclusion/Summary

May cause skin irritation.
May cause skin irritation.

Serious eye damage/eye irritation

Not available.

Conclusion/Summary [Product] Not available.

Ingredient name

L-serine
L-valine

Conclusion/Summary

May cause eye irritation.
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

Not available.

Conclusion/Summary [Product] Not available.

Specific target organ toxicity (single exposure)**Product/ingredient name**

sodium selenite

Result

SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (central nervous system (CNS), gastrointestinal tract, heart, kidneys, liver, respiratory organs) - Category 1

Specific target organ toxicity (repeated exposure)**Product/ingredient name**

sodium selenite

Result

SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) (blood system, central nervous system (CNS), hair, kidneys, liver, nails, reproductive organs (male), skin, teeth) - Category 1

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]

Effect: Population

Acute - EC50 - Fresh water

Daphnia - Water flea - *Daphnia magna* - Larvae
Age: <24 hours

374.2 mg/l [48 hours]

Effect: Intoxication

Acute - LC50 - Fresh water

Crustaceans - Water flea - *Pseudosida ramosa* - Neonate

succinic acid

potassium chloride

	Age: ≤24 hours 9.68 mg/l [48 hours] Effect: Mortality
	Acute - EC50 - Fresh water ISO Algae - Green algae - <i>Desmodesmus subspicatus</i> 9.24 g/l [72 hours] Effect: Population
	Acute - LC50 - Fresh water Fish - Zebra danio - <i>Danio rerio</i> 509.65 mg/l [96 hours] Effect: Mortality
L-serine	Acute - EC50 Daphnia 83 mg/l [48 hours]
	Acute - NOEC Algae 1000 mg/l [72 hours]
L-valine	LC50 Fish 10000 mg/l [96 hours]
sodium selenite	Acute - LC50 - Marine water Fish - Grass goby - <i>Zosterisessor ophiocephalus</i> - Adult Size: 15.6 cm; Weight: 41.7 g 0.29 ppm [96 hours] Effect: Mortality
	Acute - LC50 - Fresh water Daphnia - Water flea - <i>Daphnia pulicaria</i> Age: ≤24 hours 0.006 mg/l [48 hours] Effect: Mortality
	Chronic - NOEC - Fresh water Daphnia - Water flea - <i>Daphnia magna</i> Age: <24 hours 0.24 mg/l [21 days] Effect: Mortality
	Chronic - NOEC - Marine water Algae - Green algae - <i>Dunaliella salina</i> - Exponential growth phase Size: 3.8 to 20.3 1 mg/l [4 days] Effect: Cells
	Acute - EC50 - Fresh water Algae - Green algae - <i>Scenedesmus acutus var. acutus</i> 80 µg/l [3 days] Effect: Population
	Chronic - NOEC - Fresh water Fish - Medaka, high-eyes - <i>Oryzias latipes</i> - Juvenile (Fledgling, Hatchling, Weanling) Age: 10 days; Weight: 0.85 mg 3.936 ng/ml [210 days] Effect: Feeding Behavior

Conclusion/Summary [Product] Not available.**Ingredient name**L-serine
L-valine**Conclusion/Summary**Naturally occurring substance
Naturally occurring substancePersistence/degradability**Product/ingredient name**

L-valine

Result

82% [28 days]

Conclusion/Summary [Product] Not available.**Ingredient name**L-serine
L-valine**Conclusion/Summary**Not expected to bioaccumulate. Naturally occurring substance
Not expected to bioaccumulate. Naturally occurring substance**Product/ingredient name** **Aquatic half-life****Photolysis****Biodegradability**
Readily

L-valine

-

Bioaccumulative potential

Product/ingredient name	LogP_{ow}	BCF	Potential
succinic acid	-0.59	-	Low
L-serine	-3.07	0.609	Low
L-valine	-2.26	0.846	Low
sodium selenite	-	5.8	Low

Mobility in soil**Soil/Water partition coefficient** Not available.**Mobility** Not available.

Hazardous to the ozone layer Not 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.
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14. Transport information

	UN	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class (es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.
Additional information	-	-	-
Special precautions for user	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 IMO instruments	Not available.		

15. Regulatory information

Fire Service Law

None of the components are listed.

Fire Service Law - Obstructive materials Not listed

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

Ingredient name	%	Status	Reference number
ammonium iron(III) citrate	≤10	Listed	352, 20 * (2025-04)

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

Chemicals requiring notification

Ingredient name	%	Status	Reference number
ammonium iron(III) citrate	≤10	Listed	352, 20 * (2025-04)

ActiPRO™, with Poloxamer-188, without Insulin, without L-Glutamine, 5kg
ammonium iron(III) citrate

≤10

Listed

SH31037.09
352, 20 *
(2025-04)

* 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 Not applicable.
Appendix 1 - Dangerous Substances

Harmful Substances Subject to Obtaining Permission for Manufacturing Not listed

Harmful Substances, Prohibited for Manufacturing Not listed

Chemical Substances Control Law (CSCL)

Nickel(II) sulfate	0.000000765	Priority assessment	148
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Poisonous and Deleterious Substances

Ingredient name	%	Status	Reference number
sodium selenite	0.000135	Poisonous	1-18

Pollutant Release and Transfer Registers (PRTR)

None of the components are listed.

JSOH Carcinogen Not listed

Law concerning prevention of pollution of the ocean Not available.

Road law Not available.

List of Specially Controlled Industrial Waste Not listed

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.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

International lists

National inventory

Japan	Japan inventory (CSCL): Not determined. Japan inventory (ISHL): Not determined.
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United States Not determined.

Canada inventory Not determined.

China Not determined.

16. Other information

History

Date of printing	11/6/2025
Date of issue/Date of revision	11/6/2025
Date of previous issue	No previous validation
Version	1 sds_author@cytiva.com

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
EYE IRRITATION - Category 2A	Calculation method
HAZARDOUS TO THE AQUATIC ENVIRONMENT - ACUTE	Calculation method
HAZARD - Category 3	
HAZARDOUS TO THE AQUATIC ENVIRONMENT - CHRONIC	Calculation method
HAZARD - Category 3	

References

Not available.

 Indicates information that has changed from previously issued version.

Notice to reader

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