Safety Data Sheet

日本

1. Product and company identification

Product name **ActiSM™ with Poloxamer-188, without Insulin, without L-Glutamine, 100L**

Catalogue Number SH31038.04

Product type Powder.

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: 46.8%

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

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

Response 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	May form explosible dust-air mixture if dispersed.

3. Composition/information on ingredients

Substance/mixture Mixture

Ingredient name	含有量(%)	Identifiers	Official Gazette notice reference number	
			CSCL	ISHL
sodium chloride	<25.4	CAS: 7647-14-5	1-236	Not available.
succinic acid	<5.5	CAS: 110-15-6	2-846	Not available.
potassium chloride	<3.35	CAS: 7447-40-7	1-228	(1)-228
L-serine	<2.85	CAS: 56-45-1	9-1585	Not available.
ammonium iron(III) citrate	<2.15	CAS: 1185-57-5	2-895	Not available.
L-valine	<1.95	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. 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	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	Causes serious eye irritation.
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: 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.

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 dry chemical powder.
Unsuitable extinguishing media	Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.
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.

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. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing dust. 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. Use spark-proof tools and explosion-proof equipment. 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. Use spark-proof tools and explosion-proof equipment. 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. Avoid creating dusty conditions and prevent wind dispersal. 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 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 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 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.

8. 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 explosion-proof 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.
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. 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	Solid. [Powder.]
Color	Off-white. to Light brown.
Odor	Not available.
Odor threshold	Not available.
pH	3.1 to 3.9 [Conc. (% w/w): 2.1%]
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	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.

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 Toxic effects: 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

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)
ActiSM™ with Poloxamer-188, without Insulin, without L-Glutamine	15124.6	N/A	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

Skin corrosion/irritation

Not available.

Conclusion/Summary [Product] Not available.

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

Serious eye damage/eye irritation

Not available.

Conclusion/Summary [Product] Not available.

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

Not available.

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	Result
sodium chloride	**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
succinic acid	**Acute - EC50 - Fresh water** Daphnia - Water flea - *Daphnia magna* - Larvae Age: <24 hours 374.2 mg/l [48 hours]

	Effect: Intoxication
potassium chloride	**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
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]

Conclusion/Summary [Product] Not available.

Ingredient name	Conclusion/Summary
L-serine	Naturally occurring substance
L-valine	Naturally occurring substance

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 name	Aquatic half-life	Photolysis	Biodegradability
L-valine	-	-	Readily

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

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.

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)	*

* 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	Not applicable.

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	0.000000675	Priority assessment	148

Poisonous and Deleterious Substances

None of the components are listed.

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

References Not available.

Indicates information that has changed from previously issued version.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.
Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.