

Safety Data Sheet

Australia

Section 1. Identification

Product name

**ActiPRO™, with Poloxamer-188, without
Insulin, without L-Glutamine, 1,000 L /22,360.0
g**

Catalogue Number

SH31037.13



9 0 S H 3 1 0 3 7 . 1 3

Product type Solid.

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

Company details

Manufacturer

Cytiva Austria
Krempistr. 5
4061 Pasching
AUSTRIA
Tel. (+43) 7229 64865
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HyClone Laboratories
925 West 1800 South
Logan, Utah 84321
Phone: (435) 792-8000

Cytiva Singapore
1 Maritime Square #13-01
Harbourfront Centre
Singapore 099253

Supplier

Global Life Sciences Solutions Australia Pty Ltd
495 Blackburn Road
Mount Waverley VIC 3149
Australia
tfn: 1800 150 522

Emergency telephone number 000

Section 2. Hazard(s) identification

Classification of the substance or mixture SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2A

GHS label elements

Hazard pictograms



Signal word

WARNING

Hazard statements

Causes serious eye irritation.

Precautionary statements

Prevention	Wear eye or face protection.
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	Not applicable.
Supplemental label elements	Not applicable.

Other hazards which do not result in classification None known.

Section 3. Composition and ingredient information

Substance/mixture	Mixture
Other means of identification	Not available.

Ingredient name	% (w/w)	Identifiers
succinic acid	<5.95	CAS: 110-15-6 EC: 203-740-4
ammonium iron(III) citrate	<2.3	CAS: 1185-57-5 EC: 214-686-6

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

The total concentration of ingredients in this product, reported or not in this section, is 100%.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

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.
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.
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

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

Over-exposure signs/symptoms

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

Indication of immediate medical attention and special treatment needed, if necessary

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.
Specific treatments	No specific treatment.
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.

See toxicological information (Section 11)**Section 5. Fire-fighting measures****Extinguishing media**

Suitable extinguishing media	Use an extinguishing agent suitable for the surrounding fire.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No specific fire or explosion hazard.
Hazardous thermal decomposition products	Decomposition products may include the following materials: carbon dioxide carbon monoxide nitrogen oxides phosphorus oxides halogenated compounds metal oxide/oxides
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.

Section 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).

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.

Section 7. Handling and storage**Precautions for safe handling**

Protective measures	Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. 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.

Conditions for safe storage, including any incompatibilities	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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Section 8. Exposure controls and personal protection

Control parameters

Occupational exposure limits

Ingredient name

succinic acid

Exposure limits

DFG MAC-values list (Germany, 7/2024) Develop C.

PEAK 15 minutes: 4 mg/m³ 4 times per shift
[Interval: 1 hour]. Form: inhalable fraction.

TWA 8 hours: 2 mg/m³. Form: inhalable fraction.

Safe Work Australia (Australia, 1/2024) [Iron salts, soluble]

TWA 8 hours: 1 mg/m³ (as Fe).

Biological exposure indices

No exposure indices known.

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

Environmental exposure controls Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Hygiene measures

Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face 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

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.

Body 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.

Other skin protection

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.

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.

Section 9. Physical and chemical properties and safety characteristics

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

Appearance

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.

Burning time

Not available.

Burning rate

Not available.

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.
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.
Particle characteristics	
Median particle size	Not available.

Section 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.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result
succinic acid	Rat - Oral - LD50 2260 mg/kg
ammonium iron(III) citrate	Rat - Oral - LD50 2001 mg/kg

Conclusion/Summary [Product] Not available.

Skin corrosion/irritation

Not available.

Conclusion/Summary [Product] Not available.

Serious eye damage/eye irritation

Not available.

Conclusion/Summary [Product] Not available.

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.

Information on the likely routes of exposure Routes of entry anticipated: Oral, Dermal, Inhalation, Eyes.

Potential acute health effects

Eye contact Causes serious eye irritation.

Inhalation No known significant effects or critical hazards.

Skin contact No known significant effects or critical hazards.

Ingestion No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact Adverse symptoms may include the following:
pain or irritation
watering
redness

Inhalation No specific data.

Skin contact No specific data.

Ingestion No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure**Short term exposure**

Potential immediate effects Not available.

Potential delayed effects Not available.

Long term exposure

Potential immediate effects Not available.

Potential delayed effects Not available.

Potential chronic health effects

Not available.

Conclusion/Summary [Product]	Not available.
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General	No known significant effects or critical hazards.
Carcinogenicity	No known significant effects or critical hazards.
Mutagenicity	No known significant effects or critical hazards.
Reproductive toxicity	No known significant effects or critical hazards.

Numerical measures of toxicity**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™	81164.5	N/A	N/A	N/A	N/A
succinic acid	2260	N/A	N/A	N/A	N/A
ammonium iron(III) citrate	2001	N/A	N/A	N/A	N/A

Section 12. Ecological information**Toxicity****Product/ingredient name**

succinic acid

Result**Acute - EC50 - Fresh water**

Daphnia - Water flea - *Daphnia magna* - Larvae

Age: <24 hours

374.2 mg/l [48 hours]

Effect: Intoxication

Conclusion/Summary [Product]	Not available.
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Persistence and degradability

Not available.

Conclusion/Summary [Product]	Not available.
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Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
succinic acid	-0.59	-	Low

Mobility in soil

Soil/Water partition coefficient	Not available.
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Other adverse effects	No known significant effects or critical hazards.
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Section 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.

Section 14. Transport information

	ADG	ADR/RID	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
Proper shipping name	-	-	-	-
Class	-	-	-	-
Label				
PG	-	-	-	-
Environmental hazards	No.	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.			

Section 15. Regulatory information

Standard for the Uniform Scheduling of Medicines and Poisons

Not regulated.

Model Work Health and Safety Regulations - Scheduled Substances

No listed substance

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.

Inventory list

Australia	Not determined.
United States	Not determined.
Canada inventory	Not determined.
China	Not determined.
Japan	Japan inventory (CSCL): Not determined. Japan inventory (ISHL): Not determined.
New Zealand	Not determined.

Section 16. Any other relevant information

History

Date of printing	06 November 2025	Date of previous issue	No previous validation
Date of issue	06 November 2025	Version	1

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ADG = Australian Dangerous Goods
ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road
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
SUSMP = Standard Uniform Schedule of Medicine and Poisons
UN = United Nations

Procedure used to derive the classification

Classification	Justification
SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2A	Calculation method

 Indicates information that has changed from previously issued version.

Notice to reader

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