

SAFETY DATA SHEET

Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II, as amended by Commission Regulation (EU) 2015/830 - Europe SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name

HyClone[™] AdvanceSTEM (TM) DMEM4SC with 4500 mg/L Glucose, without L-Glutamine and Sodium Pyruvate

Catalogue Number	SH30824	
Product description	Not available.	
Product type	Liquid.	

Other means of identification

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

Not available.

Not applicable.

1.3 Details of the supplier of the safety data sheet

Suppli	ier

Cytiva Austria Kremplstr. 5 4061 Pasching AUSTRIA Phone: +43 7229 64865

HyClone Laboratories 925 West 1800 South Logan, Utah 84321 Phone; (435) 792-8000

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

Person who prepared the SDS: sds_

sds_author@cytiva.com

Europe

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Cytiva Austria Kremplstr. 5 4061 Pasching AUSTRIA Phone: +43 7229 64865

National advisory body/Poison Centre

Europe

http://www.eapcct.org -> Go to: Links

Hours of operation Mo. - Fr. 08.30 - 17.00

1.4 Emergency telephone number

Call INFOTRAC 24 Hour number: 001-352-323-3500 (CallI Collect).

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition Mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Not classified.

The product is not classified as hazardous according to Regulation (EC) 1272/2008 as amended.

Ingredients of unknown toxicity Not applicable.

Ingredients of unknown Not applicable. ecotoxicity

See Section 16 for the full text of the H statements declared above.

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements	
Hazard pictograms	
Signal word	No signal word.
Hazard statements	No known significant effects or critical hazards.
Precautionary statements	
Prevention	Not applicable.
Response	Not applicable.
Storage	Not applicable.
Disposal	Not applicable.
Hazardous ingredients	
Supplemental label elements	Not applicable.
Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	Not applicable.
Special packaging requirements	
Containers to be fitted with child-resistant fastenings	Not applicable.
Tactile warning of danger	Not applicable.
2.3 Other hazards	
Product meets the criteria for PBT Annex XIII	or vPvB according to Regulation (EC) No. 1907/2006,
Other hazards which do not result in classification	None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Mixture

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs or vPvBs or have been assigned a workplace exposure limit and hence require reporting in this section.

<u>Type</u>

[1] Substance classified with a physical, health or environmental hazard

[2] Substance with a workplace exposure limit

[3] Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII

[4] Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII

[5] Substance of equivalent concern

[6] Additional disclosure due to company policy

SECTION 4: First aid measures

4.1 Description of 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. Get medical attention if irritation occurs.	
Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.	
Skin contact	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.	
Ingestion	Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.	
Protection of first-aiders	No action shall be taken involving any personal risk or without suitable training.	

4.2 Most important symptoms and effects, both acute and delayed

Over-exposure signs/symptoms

Eye contact	No specific data.
Inhalation	No specific data.
Skin contact	No specific data.
Ingestion	No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician	Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
Specific treatments	No specific treatment.
See toxicological information (Section 11)	

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media None known.

5.2 Special hazards arising from the substance or mixture

 Hazards from the substance or mixture
 In a fire or if heated, a pressure increase will occur and the container may burst.

 Hazardous combustion products
 No specific data.

5.3 Advice for firefighters

Special precautions 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. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1 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 spilt material. Put on appropriate personal protective equipment.
For emergency responders	If specialised 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".
6.2 Environmental precautions	Avoid dispersal of spilt 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).

6.3 Methods and material for containment and cleaning up

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Small spill	Stop leak if without risk. Move containers from spill area. Dilute with water and soluble. Alternatively, or if water-insoluble, absorb with an inert dry material ar appropriate waste disposal container. Dispose of via a licensed waste disposa	nd place in an
Large spill	Stop leak if without risk. Move containers from spill area. Prevent entry into see basements or confined areas. Wash spillages into an effluent treatment plant follows. Contain and collect spillage with non-combustible, absorbent material vermiculite or diatomaceous earth and place in container for disposal accordin Dispose of via a licensed waste disposal contractor.	or proceed as e.g. sand, earth,
6.4 Reference to other sections	See Section 1 for emergency contact information. See Section 8 for information on appropriate personal protective equipment. See Section 13 for additional waste treatment information.	

SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

7.1 Precautions for safe handling

Protective measures	Put on appropriate personal protective equipment (see Section 8).
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.
7.2 Conditions for safe storage	including any incompatibilities

7.2 Conditions for safe storage, including any incompatibilities

 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 unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

 7.3 Specific end use(s)
 For further manufacturing.

 Industrial sector specific solutions
 Not available.

SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance. Information is provided based on typical anticipated uses of the product. Additional measures might be required for bulk handling or other uses that could significantly increase worker exposure or environmental releases.

8.1 Control parameters

Occupational exposure limits

No exposure limit value known.

Recommended monitoring procedures If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

No DELs available.

PNECs

No PECs available.

8.2 Exposure controls

Appropriate engineering controls

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

Individual protection measures

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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: safety glasses with side-shields.
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.
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.
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.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<u>Appearance</u>	
Physical state	Liquid.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
рН	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	Not available.
Partition coefficient: n-octanol/ water	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidising properties	Not available.
9.2 Other information	
Burning time	Not applicable.
Burning rate	Not applicable.
Solubility in water	Not available.

SECTION 10: Stability and reactivity

10.1 Reactivity 10.2 Chemical stability 10.3 Possibility of hazardous reactions	No specific test data related to reactivity available for this product or its ingredients. The product is stable. Under normal conditions of storage and use, hazardous reactions will not occur.
10.4 Conditions to avoid	No specific data.
10.5 Incompatible materials	No specific data.
10.6 Hazardous decomposition products	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicologi	cal effects			
Acute toxicity				
Conclusion/Summary	Not available.			
Acute toxicity estimates				
N/A				
Irritation/Corrosion				
Conclusion/Summary	Not available.			
<u>Sensitiser</u>				
Conclusion/Summary	Not available.			
Mutagenicity				
Conclusion/Summary	Not available.			
Carcinogenicity				
Conclusion/Summary	Not available.			
Reproductive toxicity				
Conclusion/Summary	Not available.			
<u>Teratogenicity</u>				
Conclusion/Summary	Not available.			
Specific target organ toxicity (single exposure)				
Not available.				
Specific target organ toxicity (repeated exposure)				
Not available.				
Appiration bazard				
Aspiration hazard Not available.				
Not available.				
Information on likely routes of	Routes of entry anticipated: Oral, Dermal.			
exposure				
Potential acute health effects				
Inhalation	No known significant effects or critical hazards.			
Ingestion	No known significant effects or critical hazards.			
Skin contact	No known significant effects or critical hazards.			
Eye contact	No known significant effects or critical hazards.			
Symptoms related to the physic	al, chemical and toxicological characteristics			
Inhalation	No specific data.			
Ingestion	No specific data.			
Skin contact	No specific data.			
Eye contact	No specific data.			
Delayed and immediate effects as well as chronic effects from short and long-term exposure				

Sodium Pyruvate 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	Not available.
General	No known significant effects or critical hazards.
Carcinogenicity	No known significant effects or critical hazards.
Mutagenicity	No known significant effects or critical hazards.
Teratogenicity	No known significant effects or critical hazards.
Developmental effects	No known significant effects or critical hazards.
Fertility effects	No known significant effects or critical hazards.
Other information	Not available.

SECTION 12: Ecological information

12.1 Toxicity

Conclusion/Summary Not available.

12.2 Persistence and degradability

Conclusion/Summary Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Soil/water partition coefficient Not available. (Koc) Mobility

Not available.

12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

12.6 Other adverse effects No known significant effects or critical hazards.

SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

13.1 Waste treatment methods

Product	
Methods of disposal	The generation of waste should be avoided or minimised 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.
Hazardous waste	Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC.
Packaging	
Methods of disposal	The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Sodium Pyruvate

Special precautions

This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	ΙΑΤΑ
14.1 UN number	Not available.	Not available.	Not available.	Not available.
14.2 UN proper shipping name	Not available.	Not available.	Not available.	Not available.
14.3 Transport hazard class(es)	Not available.	Not available.	Not available.	Not available.
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.
Additional information	-	-	-	-

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture <u>EU Regulation (EC) No. 1907/2006 (REACH)</u>

Annex XIV - List of substances subject to authorisation

Not available.

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

Annex XVII - Restrictions on the Not applicable. manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

Other EU regulations

Industrial emissions Not listed (integrated pollution prevention and control) - Air

Industrial emissions Not listed (integrated pollution prevention and control) -Water

Ozone depleting substances (1005/2009/EU)

Not listed.

Prior Informed Consent (PIC) (649/2012/EU)

Not listed.

Seveso Directive

This product is not controlled under the Seveso Directive.

International regulations

Article Number SH30824

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol (Annexes A, B, C, E)

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

Europe	All components are listed or exempted.
United States	Not determined.
Canada inventory	Not determined.
China	Not determined.
Japan	Japan inventory (ENCS): Not determined. Japan inventory (ISHL): Not determined.
15.2 Chemical safety assessment	This product contains substances for which Chemical Safety Assessments are still required.

SECTION 16: Other information

Indicates information that has changed from previously issued version.

N/A = Not available PBT = Persistent, Bioaccumulative and Toxic PNEC = Predicted No Effect Concentration RRN = REACH Registration Number vPvB = Very Persistent and Very Bioaccumulative	Abbreviations and acronyms	PBT = Persistent, Bioaccumulative and Toxic PNEC = Predicted No Effect Concentration RRN = REACH Registration Number	
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Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Not classified.	

Full text of abbreviated H statements	Not applicable.
Full text of classifications [CLP/ GHS]	Not applicable.
Date of printing	21 April 2020
Date of issue/ Date of revision	04 September 2018
Date of previous issue	11 February 2016
Version	2

Notice to reader

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