

# 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™ IMDM4SC

without L-Glutamine

Catalogue Number SH30822

Product descriptionNot available.Product typeLiquid.

Other means of identification Not available.

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

Not applicable.

1.3 Details of the supplier of the safety data sheet

<u>Supplier</u> 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\_author@cytiva.com

**Europe** Cytiva Austria

Kremplstr. 5 4061 Pasching AUSTRIA

Phone: +43 7229 64865

1.4 Emergency telephone number

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

Hours of operation

Mo. - Fr.

08.30 - 17.00

National advisory body/Poison Centre

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

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### 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** 

PreventionNot applicable.ResponseNot applicable.StorageNot applicable.DisposalNot applicable.

**Hazardous ingredients** 

Supplemental label elements Not applicable.

Annex XVII - Restrictions on the Not applicable.

manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

#### 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 or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII

Other hazards which do not

None known.

result in classification

### 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.

#### **Type**

- [1] Substance classified with a 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

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### SECTION 4: First aid measures

### 4.1 Description of first aid measures

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

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

mixture

Hazards from the substance or 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

Article Number SH30822 Page: 3/9 Small spill Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-

soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, Large spill

basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations.

Dispose of via a licensed waste disposal contractor.

See Section 1 for emergency contact information. 6.4 Reference to other

See Section 8 for information on appropriate personal protective equipment. sections

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).

hygiene

Advice on general occupational 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

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.

10000

5000

#### Seveso Directive - Reporting thresholds (in tonnes)

Named substances

Notification and MAPP Name Safety report threshold threshold

potassium nitrate Composite potassium-nitrate based fertilisers

composed of potassium nitrate in prilled/granular form

7.3 Specific end use(s)

Not available. Recommendations 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 and biological 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 DFI s available

#### **PNECs**

No PECs available.

#### 8.2 Exposure controls

Article Number SH30822 Page: 4/9 Appropriate engineering controls

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

#### **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.

Safety eyewear complying with an approved standard should be used when a risk assessment Eve/face protection

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.

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

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 Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk

assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected

respirator

**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

#### **Appearance**

Physical state Liquid Colour Not available Odour Not available Not available. **Odour threshold** pН Not available. Melting point/freezing point Not available. Initial boiling point and boiling Not available.

range

Flash point Not available. **Evaporation rate** Not available. Flammability (solid, gas) Not available. Upper/lower flammability or Not available.

explosive limits

Not available. Vapour pressure Vapour density Not available. Relative density Not available. Solubility(ies) Not available. Partition coefficient: n-octanol/ Not available.

water

**Auto-ignition temperature** Not available. **Decomposition temperature** Not available Not available Viscosity Not available. **Explosive properties** Oxidising properties Not available

### 9.2 Other information

**Burning time** Not applicable.

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#### HyClone™ AdvanceSTEM™ IMDM4SC without L-Glutamine

Burning rate Not applicable.

Solubility in water Not available.

### SECTION 10: Stability and reactivity

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

**10.2 Chemical stability** The product is stable.

10.3 Possibility of hazardous

reactions

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

decomposition products produced.

# **SECTION 11: Toxicological information**

# 11.1 Information on toxicological 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.

**Teratogenicity** 

Conclusion/Summary Not available.

Specific target organ toxicity (single exposure)

Not available.

### Specific target organ toxicity (repeated exposure)

Not available.

#### **Aspiration hazard**

Not available.

**Information on likely routes of** Routes of entry anticipated: Oral, Dermal.

exposure

#### Potential acute health effects

InhalationNo known significant effects or critical hazards.IngestionNo known significant effects or critical hazards.Skin contactNo known significant effects or critical hazards.Eye contactNo known significant effects or critical hazards.

### Symptoms related to the physical, chemical and toxicological characteristics

InhalationNo specific data.IngestionNo specific data.Skin contactNo specific data.Eye contactNo specific data.

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### Delayed and immediate effects as well as 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 Not available.

GeneralNo known significant effects or critical hazards.CarcinogenicityNo known significant effects or critical hazards.MutagenicityNo known significant effects or critical hazards.TeratogenicityNo known significant effects or critical hazards.Developmental effectsNo known significant effects or critical hazards.Fertility effectsNo 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**

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.

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**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	IATA
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 Not available.

### SECTION 15: Regulatory information

# 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

### EU Regulation (EC) No. 1907/2006 (REACH)

#### Annex XIV - List of substances subject to authorisation

#### **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 (integrated pollution prevention and control) - Air Not listed

**Industrial emissions** 

Not listed

(integrated pollution prevention and control) -

### Ozone depleting substances (1005/2009/EU)

Not listed.

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

Not listed.

### **Seveso Directive**

This product is controlled under the Seveso Directive.

#### Named substances

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#### Name

potassium nitrate Composite potassium-nitrate based fertilisers composed of potassium nitrate in prilled/granular form

#### International regulations

#### 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**

EuropeNot determined.United StatesNot determined.Canada inventoryNot determined.ChinaNot determined.JapanNot 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.

#### Abbreviations and acronyms

ATE = Acute Toxicity Estimate

CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]

DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level

EUH statement = CLP-specific Hazard statement

N/A = Not available

PBT = Persistent, Bioaccumulative and Toxic PNEC = Predicted No Effect Concentration RRN = REACH Registration Number

vPvB = Very Persistent and Very Bioaccumulative

#### Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Not classified.	

Full text of abbreviated H Not applicable.

statements

Full text of classifications [CLP/ Not applicable.

GHS]

Date of printing21 April 2020Date of issue/ Date of revision03 September 2015Date of previous issueNo previous validation

Version 1

### 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.

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