

SAFETY DATA SHEET

Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II, as amended by UK REACH Regulation SI 2019/758 SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

HyClone™ prime expression medium

(chemically defined), 50L

Catalogue Number SH31198.03

Product descriptionNot available.Product typePowder.Other means of identificationNot available.

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

For further manufacturing.

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

United Kingdom (UK) 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 (Call Collect).

Hours of operation

Mo. - Fr.

08.30 - 17.00

National advisory body/Poison Centre

United Kingdom (UK) National Poison Information Centre

Medical Toxicology Unit Avalonley Road London SE14 5ER Tel.: +44 (171)635 91 91

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SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition Mixture Classification according to UK CLP/GHS

Not classified.

The product is not classified as hazardous according to UK CLP Regulation SI 2019/720 as amended.

Ingredients of unknown toxicity

☑3.2 percent of the mixture consists of component(s) of unknown acute oral toxicity

62.4 percent of the mixture consists of component(s) of unknown acute dermal toxicity 69.1 percent of the mixture consists of component(s) of unknown acute inhalation toxicity

Ingredients of unknown

ecotoxicity

Contains 46.6% of components with unknown hazards to the aquatic environment

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

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

Supplemental label elements Safety data sheet available on request.

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

3.2 Mivturos

Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII

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

Other hazards which do not result in classification

May form explosible dust-air mixture if dispersed.

SECTION 3: Composition/information on ingredients

3.2 WIIXLUIES	WIXLUIE			
Product/ingredient name	Identifiers	%	Classification	Type
Z-serine	EC: 200-274-3 CAS: 56-45-1	<2.55	Aquatic Chronic 3, H412	[1]
L-valine	EC: 200-773-6 CAS: 72-18-4	<1.4	Acute Tox. 4, H302	[1]

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

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There are no additional 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, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

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

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

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. 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

Skin contact Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get

medical attention if symptoms occur.

Wash out mouth with water. If material has been swallowed and the exposed person is conscious, Ingestion

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 Adverse symptoms may include the following:

irritation

redness

Inhalation Adverse symptoms may include the following:

respiratory tract irritation

coughing

Skin contact No specific data. No specific data. Ingestion

4.3 Indication of any immediate medical attention and special treatment needed

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.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or May form explosible dust-air mixture if dispersed.

mixture

Hazardous combustion

products

Decomposition products may include the following materials:

carbon dioxide carbon monoxide nitrogen oxides sulfur oxides phosphorus oxides halogenated compounds metal oxide/oxides

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

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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. Shut off all ignition sources. No flares, smoking or flames in hazard

area. Avoid breathing dust. Put on appropriate personal protective equipment.

For emergency responders

If specialised clothing is required to deal with the spillage, take note of any infor

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

Small spill Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Vacuum or

sweep up material and place in a designated, labelled 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

the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Vacuum or sweep up material and place in a designated, labelled waste container. Avoid creating dusty conditions and prevent wind dispersal. Dispose of via a licensed waste disposal contractor.

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). Avoid breathing dust. 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. 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 earthing and bonding containers and equipment before transferring material.

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

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 oxidising 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 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)

Recommendations Not available.

Industrial sector specific Not available.

solutions

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits

No exposure limit value known.

Biological exposure indices

No exposure indices known.

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Recommended monitoring procedures

Reference should be made to monitoring standards, such as the following: British Standard BS EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) British Standard BS EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) British Standard BS 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

Product/ingredient name

Z-serine

L-valine

Result

DNEL - General population - Long term - Oral

37.5 mg/kg bw/day Effects: Systemic

DNEL - General population - Long term - Inhalation

130 mg/m³ Effects: Systemic

DNEL - General population - Long term - Dermal

375 mg/kg bw/day Effects: Systemic

DNEL - Workers - Long term - Inhalation

529 mg/m³ Effects: Systemic

DNEL - Workers - Long term - Dermal

750 mg/kg bw/day Effects: Systemic

DNEL - General population - Long term - Oral

7.9 mg/kg bw/day Effects: Systemic

DNEL - General population - Long term - Inhalation

27.3 mg/m³ Effects: Systemic

DNEL - General population - Long term - Dermal

78.5 mg/kg bw/day Effects: Systemic

DNEL - Workers - Long term - Inhalation

110.7 mg/m³ Effects: Systemic

DNEL - Workers - Long term - Dermal

157 mg/kg bw/day Effects: Systemic

PNECs

Not available.

8.2 Exposure controls

Appropriate engineering

controls

Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapour 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, vapour or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.

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: safety glasses with side-shields. If operating conditions cause high dust

concentrations to be produced, use dust 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.

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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 protectionBased 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

Body protection

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

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

9.1 Information on basic physical and chemical properties

Appearance

Physical state Solid. [Powder.]
Colour Off-white.

Odour Not available.

Odour threshold Not available.

pH 5.2 to 7.4

Melting point/freezing point Not available.

Initial boiling point and boiling Not available.

range

Flammability (solid, gas)

Upper/lower flammability or explosive limits

Not available.

Not applicable.

Flash point Not applicable.

Auto-ignition temperature Not applicable.

Decomposition temperature Not available.

 Decomposition temperature
 Not available.

 Viscosity
 Dynamic (room temperature): Not available.

Kinematic (room temperature): Not available.

Kinematic (40°C): Not available.

Solubility in water
Partition coefficient: n-octanol/

water

Not available.

Not applicable.

Vapour pressureNot available.Evaporation rateNot available.Relative densityNot available.Vapour densityNot applicable.Explosive propertiesNot available.Oxidising propertiesNot available.

Particle characteristics

Median particle size Not available.

9.2 Other information

Not available.

Burning timeNot available.Burning rateNot available.Solubility in waterNot available.

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SH31198.03

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.

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 earthing and bonding containers and equipment before

transferring material. Prevent dust accumulation.

Reactive or incompatible with the following materials: oxidising materials

Oxidising materials

10.6 Hazardous

10.5 Incompatible materials

10.4 Conditions to avoid

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

Product/ingredient name Result

₹-serine **Rat - Oral - LD50**

14 g/kg

L-valine Rat - Oral - LD50

2000 mg/kg

Conclusion/Summary [Product] Not available.

Acute toxicity estimates

Product/ingredient name	Oral (mg/ kg)	Dermal (mg/ kg)	Inhalation (gases) (ppm)	Inhalation (vapours) (mg/l)	Inhalation (dusts and mists) (mg/
HyClone™ prime expression medium (chemically defined)	112594.7	N/A	N/A	N/A	N/A
L-serine	14000	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.

Serious eye damage/eye irritation

Not available.

Conclusion/Summary [Product] Not available.

Ingredient nameConclusion/Summary€-serineMay cause eye irritation.L-valineMay cause eye irritation.

Respiratory corrosion/irritation

Not available.

Conclusion/Summary [Product] Not available.

Respiratory or skin sensitization

Not available.

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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 likely routes of

Routes of entry anticipated: Oral, Dermal, Eyes.

exposure

Potential acute health effects

Inhalation Exposure to airborne concentrations above statutory or recommended exposure limits may cause

irritation of the eyes.

Ingestion No known significant effects or critical hazards. Skin contact No known significant effects or critical hazards.

Eye contact Exposure to airborne concentrations above statutory or recommended exposure limits may cause

irritation of the eyes.

Symptoms related to the physical, chemical and toxicological characteristics

Inhalation Adverse symptoms may include the following:

respiratory tract irritation

coughing

Ingestion No specific data. Skin contact No specific data.

Eye contact Adverse symptoms may include the following:

irritation

redness

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

Article Number 31141433 Page: 8/12 Potential immediate effects Not available.

Potential delayed effects Not available.

Potential chronic health effects

Not available.

Conclusion/Summary [Product] Not available.

General Repeated or prolonged inhalation of dust may lead to chronic respiratory irritation.

CarcinogenicityNo known significant effects or critical hazards.MutagenicityNo known significant effects or critical hazards.Reproductive toxicityNo known significant effects or critical hazards.

Other information Not available.

SECTION 12: Ecological information

12.1 Toxicity

Product/ingredient name Result

✓-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

 ₹-serine
 Naturally occurring substance

 L-valine
 Naturally occurring substance

12.2 Persistence and degradability

Product/ingredient name Result

V-valine 82% [28 days]

Conclusion/Summary [Product] Not available.

Ingredient name Conclusion/Summary

√E-serine Not expected to bioaccumulate. Naturally occurring substance Not expected to bioaccumulate. Naturally occurring substance

L-valine Not expected to bioaccumulate. Naturally occurring substance

Not expected to bioaccumulate.

N

Product/ingredient name Aquatic half-life Photolysis Biodegradability

₹-valine - - Readily

12.3 Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
 ₹3 ≤3	-3.07	0.609	Low
	-2.26	0.846	Low

12.4 Mobility in soil

Soil/water partition coefficient Not available.

Mobility Not available.

12.5 Results of PBT and vPvB assessment

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

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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

Special precautions

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.

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 IMO instruments

Not available.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture UK (GB)/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.

Ozone depleting substances

Not listed.

Prior Informed Consent (PIC)

Not listed.

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Persistent Organic Pollutants

Not listed.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

Product/ingredient name % Designation [Usage]

Molybdate (Mo7O246-), ammonium, hydrate (1:6: ≤0.1 65

4)

Cadmium chloride, hydrate (2:5) ≤0.02 23

Labelling Not applicable.

Seveso Directive

This product is not controlled under the Seveso Directive.

EU regulations

Industrial emissions Not listed

(integrated pollution prevention and control) - Air

Industrial emissions Not listed

(integrated pollution prevention and control) - Water

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

United States Not determined.

Canada inventory Not determined.

China At least one component is not listed.

Japan Japan inventory (CSCL): Not determined.

Japan inventory (ISHL): Not determined.

15.2 Chemical safety

assessment

 $\label{thm:contains} \begin{tabular}{ll} This product contains substances for which Chemical Safety Assessments are still required. \\ \end{tabular}$

SECTION 16: Other information

Indicates information that has changed from previously issued version.

Abbreviations and acronyms ATE = Acute Toxicity Estimate

GB CLP = UK CLP (EC No 1272/2008) on the Classification, Labelling and Packaging of Substances and Mixtures as amended by (EU Exit) Regulations 2019 No. 720 and amendments

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

EUH statement = GB CLP-specific Hazard statement

N/A = Not available

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

SGG = Segregation Group

vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification

Classification	Justification
Not classified.	

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Full text of abbreviated H H302 Harmful if swallowed.

Harmful to aquatic life with long lasting effects. statements H412

Full text of classifications Acute Tox. 4

ACUTE TOXICITY - Category 4 LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 3 Aquatic Chronic 3

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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

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