

SAFETY DATA SHEET

Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II, as amended by Commission Regulation (EU) 2015/830 - Switzerland

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

RPMI-1640, Autoclavable, without L-

Glutamine or Sodium Bicarbonate

Catalogue Number SH30328

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

Switzerland Cytiva Austria

Kremplstr. 5 4061 Pasching AUSTRIA

Phone: +43 7229 64865

National advisory body/Poison Centre

Switzerland Schweizerisches Toxikologische

Informationszentrum Freiestrasse 16 8032 Zürich

Tel.: +41 (1) 251 51 51

Hours of operation

Mo. - Fr. 08.30 - 17.00

1.4 Emergency telephone number

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

Article Number SH30328 Page: 1/10

Version 2

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

90.2 percent of the mixture consists of component(s) of unknown acute dermal toxicity 90.2 percent of the mixture consists of component(s) of unknown acute inhalation toxicity

Ingredients of unknown

ecotoxicity

Contains 22.9 % 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.

Precautionary statements

 Prevention
 Not applicable.

 Response
 Not applicable.

 Storage
 Not applicable.

 Disposal
 Not applicable.

Hazardous ingredients

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

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

			Classification	
Product/ingredient name	Identifiers	%	Regulation (EC) No. 1272/2008 [CLP]	Туре
Nitric acid, calcium salt, tetrahydrate	EC: 233-332-1 CAS: 13477-34-4	<1.1	Ox. Sol. 3, H272 STOT SE 2, H371 STOT RE 2, H373 See Section 16 for the full text of the H statements declared above.	[1]

Article Number SH30328 Page: 2/10

Version 2

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 or vPvBs or have been assigned a workplace exposure limit and hence require reporting in this section.

Type

- $\cline{1}$ 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

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

SECTION 4: First aid measures

4.1 Description of first aid measures

Eye contact mmediately 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

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

hours.

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

medical attention if symptoms occur.

Ingestion

₩ash 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 Adverse symptoms may include the following:

irritation redness

Inhalation Adverse symptoms may include the following:

respiratory tract irritation

coughing

Skin contactNo specific data.IngestionNo specific data.

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.

See toxicological information (Section 11)

SECTION 5: Firefighting measures

5.1 Extinguishing media

Unsuitable extinguishing media void 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 Decomposition products may include the following materials:

products carbon dioxide

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

5.3 Advice for firefighters

Article Number SH30328 Page: 3/10

Special precautions for firefighters Fromptly 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 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 involv

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 information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

6.2 Environmental precautions

Kvoid 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 unwind. Provent entry into source, water equipment are enfined areas.

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

Fut 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 oxidizing materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in 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

For Further Manufacturing or Research Use. Not for Diagnostic or Therapeutic Use.

Industrial sector specific

solutions

Not available.

Article Number SH30328 Page: 4/10

Version 2

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 DELs available.

PNECs

No PECs 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.

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

Appearance

Physical state Solid. [Powder.]
Colour Not available.
Odour Not available.
Odour threshold Not available.
pH Not available.

Article Number SH30328 Page: 5/10

RPMI-1640, Autoclavable, without L-Glutamine or Sodium Bicarbonate

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 explosive limits

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

water

tanol/

water

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Explosive properties Explosive in the presence of the following materials or conditions: combustible materials, organic

materials and metals.

Oxidising properties Not available.

9.2 Other information

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

10.5 Incompatible materials Reactive or incompatible with the following materials:

oxidizing materials

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 toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Mitric acid, calcium salt, tetrahydrate	LD50 Oral	Rat	3900 mg/kg	-

Conclusion/Summary 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/ I)
Nitric acid, calcium salt, tetrahydrate	3900	N/A	N/A	N/A	N/A

Irritation/Corrosion

Article Number SH30328 Page: 6/10
Validation date 24 July 2019

RPMI-1640, Autoclavable, without L-Glutamine or Sodium Bicarbonate

Conclusion/Summary

Not available.

Sensitiser

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)

Product/ingredient name	Category	Route of exposure	Target organs
Nitric acid, calcium salt, tetrahydrate	Category 2	Not determined	Not determined

Specific target organ toxicity (repeated exposure)

Product/ingredient name	Category	Route of exposure	Target organs
Nitric acid, calcium salt, tetrahydrate	Category 2	Not determined	Not determined

Aspiration hazard

Not available.

Information on likely routes of

exposure

Routes of entry anticipated: Oral, Dermal, Inhalation.

Potential acute health effects

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

irritation of the nose, throat and lungs.

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

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

IngestionNo specific data.Skin contactNo specific data.

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

Potential immediate effects Not available.

Potential delayed effects Not available.

Potential chronic health effects

Not available.

Conclusion/Summary Not available.

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

Carcinogenicity No known significant effects or critical hazards.

Article Number SH30328 Page: 7/10

PMI-1640, Autoclavable, without L-Glutamine or Sodium Bicarbonate

No known significant effects or critical hazards. Mutagenicity 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

Product/ingredient name	Result	Species	Exposure
Nitric acid, calcium salt, tetrahydrate	LC50 >98.9 mg/l	Fish	96 hours

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

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.

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 regulated.	Not available.	Not available.
14.2 UN proper shipping name	Not available.		Not available.	Not available.

Article Number SH30328 Page: 8/10

RPMI-1640, Autoclavable, without L-Glutamine or Sodium Bicarbonate

14.3 Transport hazard class(es)	Not available.		₹ot available.	Not available.
14.4 Packing group	V	"	"	"
14.5 Environmental hazards	N o.	N o.	N o.	N o.
Additional information		V	V	V

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 Not listed (integrated pollution

prevention and control) - Air

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

Ozone depleting substances (1005/2009/EU)

Not listed.

Water

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

Not listed.

Seveso Directive

This product is not controlled under the Seveso Directive.

National regulations

VOC content Exempt.

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)

Article Number SH30328 Page: 9/10

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 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.

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.	

H373 May cause damage to organs through prolonged or repeated exposure.

Full text of classifications [CLP/ Ox. Sol. 3, H272

GHS]

Øx. Sol. 3, H272OXIDISING SOLIDS - Category 3STOT RE 2, H373SPECIFIC TARGET ORGAN TOX

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE -

Category 2

STOT SE 2, H371 SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE -

Category 2

Date of printing15 April 2020Date of issue/ Date of revision24 July 2019Date of previous issue28 December 2015

Version 2

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.

Article Number SH30328 Page: 10/10