

KIT SAFETY DATA SHEET



Kit Product Name Lyphocheck Quantitative Urine Control

Kit Catalogue Number(s) 375X

Revision date 12-Oct-2021

Kit Contents

Catalogue Number(s)	Product Name
376	Lyphocheck Quantitative Urine Control, Level 1
377	Lyphocheck Quantitative Urine Control, Level 2



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
The Globally Harmonised System of Classification and Labelling of Chemicals (GHS)

Revision date 12-Oct-2021

Revision Number 1

1. IDENTIFICATION

Product identifier

Product Name Lyphocheck Quantitative Urine Control, Level 1

Other means of identification

Catalogue Number(s) 376

Registration Number(s) No information available

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic

Supplier's details

Corporate Headquarters

Bio-Rad Laboratories Inc.
1000 Alfred Nobel Drive
Hercules, CA 94547
USA

Manufacturer

Bio-Rad Laboratories Inc.
9500 Jeronimo Road
Irvine, California 92618
USA

Legal Entity / Contact Address

Bio-Rad Laboratories Pvt. Ltd.
Bio-Rad House
86-87, Udyog Vihar Phase IV Gurgaon
122005
Haryana India

Bio-Rad Laboratories (Pty) Ltd.
34 Bolton Road
Parkwood, Johannesburg 2193
South Africa

Technical Service

India: 91-124-4029300 or 1-800-180-1224
South Africa: 27-11-442-85-08
India: support.india@bio-rad.com
South Africa: cdg_techsupport_eemea@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC India: 000-800-100-7141
CHEMTREC South Africa: 0-800-983-611

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS)

GHS Label elements, including precautionary statements

Other hazards which do not result in classification

No information available

Contains human source material and / or potentially infectious components

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance

Not applicable

Mixture**4. FIRST AID MEASURES**Description of necessary first aid measures

Inhalation	Remove to fresh air.
Skin contact	Wash with soap and water.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Ingestion	Call a physician.

For emergency responders

Self-protection of the first aider	No information available.
------------------------------------	---------------------------

Most important symptoms and effects, both acute and delayed

Symptoms	No information available.
----------	---------------------------

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

Note to physicians	Treat symptomatically.
--------------------	------------------------

5. FIREFIGHTING MEASURESSuitable Extinguishing Media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
------------------------------	---

Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
------------	--

Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
--------------------------------	---

Specific hazards arising from the chemical

Specific hazards arising from the chemical	No information available.
--	---------------------------

Special protective actions for fire-fighters

Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
--	--

6. ACCIDENTAL RELEASE MEASURESPersonal precautions, protective equipment and emergency procedures

Personal precautions	Ensure adequate ventilation.
----------------------	------------------------------

Environmental precautions

Environmental precautions	See Section 12 for additional Ecological Information.
---------------------------	---

Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
-------------------------	---

Methods for cleaning up	Clean contaminated surface thoroughly.
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice.
--------------------------------	--

Conditions for safe storage, including any incompatibilities

Storage Conditions	Keep containers tightly closed in a dry, cool and well-ventilated place.
---------------------------	--

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure guidelines	This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies
----------------------------	--

Appropriate engineering controls

Engineering controls	Showers Eyewash stations Ventilation systems.
-----------------------------	---

Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields (or goggles).
Skin and body protection	Wear suitable protective clothing.
Hand protection	Wear suitable gloves.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Solid	Odour	Slight
Appearance	powder or cake, lyophilised	Odour threshold	No information available
Colour	light yellow		
Property	Values	Remarks • Method	
pH	6.3	No information available	
Melting point / freezing point		No information available	
Boiling point / boiling range		No information available	
Flash point		No information available	
Evaporation rate		No information available	
Flammability (solid, gas)		No information available	
Upper/lower flammability or explosive limits			
Upper flammability or explosive limits	Not applicable		
Lower flammability or explosive limits	Not applicable		
Vapour pressure		No information available	
Vapour density		No information available	

Relative density	No information available
Solubility(ies)	
Water solubility	Soluble in water
Solubility in other solvents	No information available
Partition coefficient	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available
Viscosity	
Kinematic viscosity	No information available
Dynamic viscosity	

Other information

Oxidising properties	Not applicable
----------------------	----------------

10. STABILITY AND REACTIVITY**Reactivity**

Reactivity	No information available.
------------	---------------------------

Chemical stability

Stability	Stable under normal conditions.
-----------	---------------------------------

Explosion data

Sensitivity to mechanical impact	None
Sensitivity to static discharge	None.

Possibility of hazardous reactions

Possibility of hazardous reactions	None under normal processing.
------------------------------------	-------------------------------

Conditions to avoid

Conditions to avoid	None known based on information supplied.
---------------------	---

Incompatible materials

Incompatible materials	None known based on information supplied.
------------------------	---

Hazardous decomposition products

Hazardous decomposition products	None known based on information supplied.
----------------------------------	---

11. TOXICOLOGICAL INFORMATION**Information on the likely routes of exposure****Product Information**

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

Symptoms	No information available.
----------	---------------------------

Acute toxicity**Numerical measures of toxicity**

10.405 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
76.5896 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
89.6426 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
89.6426 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
89.6426 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral)	5,058.70 mg/kg
ATEmix (dermal)	8,330.10 mg/kg

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

Skin corrosion/irritation	No information available.
Serious eye damage/irritation	No information available.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.

12. ECOLOGICAL INFORMATION

Toxicity

0 % of the mixture consists of component(s) of unknown hazards to the aquatic environment

Ecotoxicity

Persistence and degradability

No information available.

Bioaccumulative potential

There is no data for this product.

Mobility

Mobility in soil	No information available.
Mobility	No information available.

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues/unused products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
Contaminated packaging	Do not reuse empty containers.

14. TRANSPORT INFORMATION

<u>IMDG</u>	Not regulated
Transport in bulk according to Annex II of MARPOL and the IBC Code	No information available
<u>IATA</u>	Not regulated
<u>RID</u>	Not regulated
<u>ADR</u>	Not regulated
<u>ADN</u>	Not regulated
Special precautions for user	Special provisions from the regulations relative to the specified mode of transport are noted by numeric code. Refer to the regulations for the full text of special provisions.

15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture****International Regulations**

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

International Inventories

Contact supplier for inventory compliance status

16. OTHER INFORMATION

Prepared By	Bio-Rad Laboratories, Environmental Health and Safety
Revision date	12-Oct-2021
Revision Note	*** Indicates this information has changed since the previous revision.

Key or legend to abbreviations and acronyms used in the safety data sheet**Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation
C	Carcinogen		

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of Safety Data Sheet



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
The Globally Harmonised System of Classification and Labelling of Chemicals (GHS)

Revision date 12-Oct-2021

Revision Number 1

1. IDENTIFICATION

Product identifier

Product Name Lyphocheck Quantitative Urine Control, Level 2

Other means of identification

Catalogue Number(s) 377

Registration Number(s) No information available

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic

Supplier's details

Corporate Headquarters

Bio-Rad Laboratories Inc.
1000 Alfred Nobel Drive
Hercules, CA 94547
USA

Manufacturer

Bio-Rad Laboratories Inc.
9500 Jeronimo Road
Irvine, California 92618
USA

Legal Entity / Contact Address

Bio-Rad Laboratories Pvt. Ltd.
Bio-Rad House
86-87, Udyog Vihar Phase IV Gurgaon
122005
Haryana India

Bio-Rad Laboratories (Pty) Ltd.
34 Bolton Road
Parkwood, Johannesburg 2193
South Africa

Technical Service

India: 91-124-4029300 or 1-800-180-1224
South Africa: 27-11-442-85-08
India: support.india@bio-rad.com
South Africa: cdg_techsupport_eemea@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC India: 000-800-100-7141
CHEMTREC South Africa: 0-800-983-611

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

Acute toxicity - Oral

Category 5

GHS Label elements, including precautionary statements

Signal word

Warning

Hazard statements

May be harmful if swallowed

Other hazards which do not result in classification

No information available

Contains human source material and / or potentially infectious components

3. COMPOSITION/INFORMATION ON INGREDIENTS**Substance**

Not applicable

Mixture

Chemical name	CAS No	Weight-%
Sodium chloride 7647-14-5	7647-14-5	20.486
Trade secret	-	10 - 20%
Trade secret	-	0 - 10%

4. FIRST AID MEASURES**Description of necessary first aid measures**

Inhalation	Remove to fresh air.
Skin contact	Wash skin with soap and water. Wash with soap and water.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Ingestion	Call a physician.

For emergency responders

Self-protection of the first aider	No information available.
------------------------------------	---------------------------

Most important symptoms and effects, both acute and delayed

Symptoms	No information available.
----------	---------------------------

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

Note to physicians	Treat symptomatically.
--------------------	------------------------

5. FIREFIGHTING MEASURES**Suitable Extinguishing Media**

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
------------------------------	---

Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
------------	--

Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
--------------------------------	---

Specific hazards arising from the chemical

Specific hazards arising from the chemical	No information available.
--	---------------------------

Special protective actions for fire-fighters

Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
--	--

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Clean contaminated surface thoroughly.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure guidelines This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Skin and body protection Wear suitable protective clothing.

Hand protection Wear suitable gloves.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Solid	Odour	Slight
Appearance	powder or cake, lyophilised	Odour threshold	No information available
Colour	light yellow		

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	6.3	
Melting point / freezing point		No information available
Boiling point / boiling range		No information available
Flash point		No information available
Evaporation rate		No information available
Flammability (solid, gas)		No information available
Upper/lower flammability or explosive limits		
Upper flammability or explosive limits	Not applicable	
Lower flammability or explosive limits	Not applicable	
Vapour pressure		No information available
Vapour density		No information available
Relative density		No information available
Solubility(ies)		
Water solubility	Soluble in water	
Solubility in other solvents		No information available
Partition coefficient		No information available
Autoignition temperature		No information available
Decomposition temperature		No information available
Viscosity		
Kinematic viscosity		No information available
Dynamic viscosity		

Other information

Oxidising properties	Not applicable
----------------------	----------------

10. STABILITY AND REACTIVITY

Reactivity

Reactivity	No information available.
------------	---------------------------

Chemical stability

Stability	Stable under normal conditions.
-----------	---------------------------------

Explosion data

Sensitivity to mechanical impact	None
Sensitivity to static discharge	None.

Possibility of hazardous reactions

Possibility of hazardous reactions	None under normal processing.
------------------------------------	-------------------------------

Conditions to avoid

Conditions to avoid	None known based on information supplied.
---------------------	---

Incompatible materials

Incompatible materials	None known based on information supplied.
------------------------	---

Hazardous decomposition products

Hazardous decomposition products	None known based on information supplied.
----------------------------------	---

11. TOXICOLOGICAL INFORMATION

Information on the likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion May be harmful if swallowed.

Symptoms No information available.

Acute toxicity

Numerical measures of toxicity

7.925 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
 67.6796 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
 95.2446 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
 95.2446 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
 74.7586 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral) 4,878.80 mg/kg
ATEmix (dermal) 21,205.90 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium chloride	= 3 g/kg (Rat)	> 10 g/kg (Rabbit)	> 42 g/m ³ (Rat) 1 h
Trade secret	= 2600 mg/kg (Rat)	-	-
Trade secret	= 4280 mg/kg (Rat)	-	-

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

Skin corrosion/irritation No information available.

Serious eye damage/irritation No information available.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

12. ECOLOGICAL INFORMATION

Toxicity

0 % of the mixture consists of component(s) of unknown hazards to the aquatic environment

Ecotoxicity

Chemical name	Algae/aquatic plants	Fish	Crustacea
---------------	----------------------	------	-----------

Sodium chloride	-	LC50: 4747 - 7824mg/L (96h, <i>Oncorhynchus mykiss</i>) LC50: 5560 - 6080mg/L (96h, <i>Lepomis macrochirus</i>) LC50: 6020 - 7070mg/L (96h, <i>Pimephales promelas</i>) LC50: 6420 - 6700mg/L (96h, <i>Pimephales promelas</i>) LC50: =12946mg/L (96h, <i>Lepomis macrochirus</i>) LC50: =7050mg/L (96h, <i>Pimephales promelas</i>)	EC50: 340.7 - 469.2mg/L (48h, <i>Daphnia magna</i>) EC50: =1000mg/L (48h, <i>Daphnia magna</i>)
Trade secret	EC50: =2500mg/L (72h, <i>Desmodemus subspicatus</i>)	LC50: 750 - 1020mg/L (96h, <i>Pimephales promelas</i>) LC50: =1060mg/L (96h, <i>Lepomis macrochirus</i>)	EC50: =825mg/L (48h, <i>Daphnia magna</i>) EC50: =83mg/L (48h, <i>Daphnia magna</i>)

Persistence and degradability

No information available.

Bioaccumulative potential

There is no data for this product.

Mobility

Mobility in soil No information available.

Mobility No information available.

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

14. TRANSPORT INFORMATION

IMDG Not regulated
Transport in bulk according to Annex II of MARPOL and the IBC Code No information available

IATA Not regulated

RID Not regulated

ADR Not regulated

ADN Not regulated

Special precautions for user Special provisions from the regulations relative to the specified mode of transport are noted by numeric code. Refer to the regulations for the full text of special provisions.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture**International Regulations**

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

International Inventories

Contact supplier for inventory compliance status

16. OTHER INFORMATION

Prepared By Bio-Rad Laboratories, Environmental Health and Safety

Revision date 12-Oct-2021

Revision Note *** Indicates this information has changed since the previous revision.

Key or legend to abbreviations and acronyms used in the safety data sheet**Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation
C	Carcinogen		

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of Safety Data Sheet