

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:
GB/T 16483-2008, GB/T 17519-2013

Product Name Lyphochek Quantitative Urine Control, Level 1

Revision date 12-Oct-2021

Revision Number 1

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

Product identifier

Product Name Lyphochek Quantitative Urine Control, Level 1

Catalogue Number(s) 376

Other means of identification

Pure substance/mixture Mixture

Details of the supplier of the safety data sheet

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 Ltd.
1st and 2nd Floor, Lumpini 1 Building
239/2, Rajdamri Road, Lumpini,
Pathumwan, Bangkok 10330
Thailand

Technical Service +66 2 652 8313
ctsthailand@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Hong Kong: 800-968-793

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic

SECTION 2: Hazards identification

Emergency Overview

No significant adverse health effects

Appearance powder or cake, lyophilised **Physical state** Solid **Odour** Slight

Classification of the substance or mixture

Not classified

Label elements

Hazard statements

Not classified

Physical and chemical hazards

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Not applicable.

Health hazards

Immediate Health Effects: Not applicable.

Chronic effects: Not applicable.

Environmental hazards

Not applicable

Other hazards which do not result in classification

Contains animal source material Contains components derived from human urine

Contains human source material and / or potentially infectious components.

SECTION 3: Composition/information on ingredients

Substance

Not applicable.

Mixture

Not classified.

SECTION 4: First aid measures

Description of necessary first aid measures

General advice	Contains components derived from human urine.
Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a doctor.
Skin contact	Wash with soap and water.
Ingestion	Call a doctor. Contains human source material and / or potentially infectious components.
<u>Most important symptoms and effects, both acute and delayed</u>	No information available.
<u>For emergency responders</u>	No information available.
<u>Note to doctors</u>	Contains human source material and / or potentially infectious components.

SECTION 5: Firefighting measures

Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	No information available.
<u>Specific hazards arising from the chemical</u>	No information available.

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<u>Special protective actions for fire-fighters</u>	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions	See section 8 for more information.
For emergency responders	Use personal protection recommended in Section 8.
<u>Environmental precautions</u>	See Section 12 for additional Ecological Information.
<u>Methods and material for containment and cleaning up</u>	Do not allow into any sewer, on the ground or into any body of water. Clean contaminated surface thoroughly. Use: Disinfectant.
<u>Precautions to prevent secondary hazards</u>	Clean contaminated objects and areas thoroughly observing environmental regulations.

SECTION 7: Handling and storage

<u>Precautions for safe handling</u>	Handle in accordance with good industrial hygiene and safety practice. Follow universal and standard precautions for handling potentially infectious materials. See Section 8 for information on appropriate personal protective equipment.
<u>Conditions for safe storage, including any incompatibilities</u>	Store according to product and label instructions.
Incompatible materials	None known based on information supplied.

SECTION 8: Exposure controls/personal protection

Occupational exposure limits

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

Note	See section 16 for terms and abbreviations
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Biological occupational exposure limits

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

Monitoring and observation processes

If the referenced standard is not applicable at the point where the product is used, a suitable equivalent standard published by local standards organisations or competent authorities should be consulted.

<u>Engineering controls</u>	Showers Eyewash stations Ventilation systems.
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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.

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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 Follow universal and standard precautions for handling potentially infectious materials.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

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

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	5.5-7.0	
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapour pressure	No data available	None known
Vapour density	No data available	None known
Relative density	No data available	None known
Water solubility	Soluble in water	
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known

Additional information

Explosive properties Not applicable
Oxidising properties Not applicable

SECTION 10: Stability and reactivity

Stability Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Sensitivity to mechanical impact None.
Sensitivity to static discharge None.

Conditions to avoid None known based on information supplied.

Incompatible materials None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

Acute toxicity

Numerical measures of toxicity

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

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Carcinogenicity Based on available data, the classification criteria are not met.

Legend

IARC (International Agency for Research on Cancer)

Group 1 - Carcinogenic to Humans

Group 2A - Probably Carcinogenic to Humans

Group 3 - Not Classifiable as to Carcinogenicity in Humans

Reproductive toxicity Based on available data, the classification criteria are not met.

Specific target organ toxicity — single exposure Based on available data, the classification criteria are not met.

Specific target organ toxicity — repeated exposure Based on available data, the classification criteria are not met.

Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

Ecotoxicity

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

Persistence and degradability No information available.

Bioaccumulative potential There is no data for this product.

Mobility in soil No information available.

SECTION 13: Disposal considerations

Waste chemicals Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

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SECTION 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
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China	Not regulated
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Special precautions for user

Please refer to the applicable dangerous goods regulations for additional information

SECTION 15: Regulatory information

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

National regulations

Law of the People's Republic of China on Prevention and Control of Occupational Diseases

Catalogue of occupational hazard factors:	Not applicable.
Catalogue of occupational diseases:	Not applicable.

Regulations on the Control over Safety of Hazardous Chemicals

<u>Inventory of hazardous chemicals</u>	Not applicable.
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<u>GB 18218-2009 Identification of major hazard installations for dangerous chemicals</u>	Not applicable
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List of hazardous chemicals under priority management	Not applicable
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Regulations on Labour Protection in Workplaces Where Toxic Substances Are Used

Inventory of highly toxic goods	Not applicable
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Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

List of toxic chemicals severely restricted for import and export in China	Not applicable
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Measures for the Environmental Management of New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances	Contact supplier for inventory compliance status.
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International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer	Not applicable
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The Stockholm Convention on Persistent Organic Pollutants	Not applicable
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The Rotterdam Convention	Not applicable
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SECTION 16: Other information

Prepared By	Bio-Rad Laboratories, Environmental Health and Safety
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Revision date	12-Oct-2021
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Revision Note	Significant changes throughout SDS. Review all sections.
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Abbreviations and acronyms

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		

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AEGL(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification
Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications
Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme
Organisation for Economic Co-operation and Development Screening Information Data Set
RTECS (Registry of Toxic Effects of Chemical Substances)
World Health Organization

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:
GB/T 16483-2008, GB/T 17519-2013

Product Name Lyphochek Quantitative Urine Control, Level 2
Revision date 12-Oct-2021
Revision Number 1

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

Product identifier

Product Name Lyphochek Quantitative Urine Control, Level 2
Catalogue Number(s) 377

Other means of identification

Pure substance/mixture Mixture

Details of the supplier of the safety data sheet

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 Ltd.
1st and 2nd Floor, Lumpini 1 Building
239/2, Rajdamri Road, Lumpini,
Pathumwan, Bangkok 10330
Thailand

Technical Service +66 2 652 8313
ctsthailand@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Hong Kong: 800-968-793

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic

SECTION 2: Hazards identification

Emergency Overview

No significant adverse health effects

Appearance powder or cake, lyophilised **Physical state** Solid **Odour** Slight

Classification of the substance or mixture

Acute toxicity - Oral	Category 5
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Label elements

Signal word Warning
Revision date 12-Oct-2021

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Revision date 12-Oct-2021

(M)SDS Number

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Hazard statements

May be harmful if swallowed

Precautionary statements

Physical and chemical hazards

Not applicable.

Health hazards

Immediate Health Effects: If large quantities of this material are swallowed, call a doctor immediately. If symptoms persist, call a doctor.

Chronic effects: Not applicable.

Environmental hazards

Not applicable

Other hazards which do not result in classification

Contains components derived from human urine Contains animal source material

Contains human source material and / or potentially infectious components.

SECTION 3: Composition/information on ingredients

Substance

Not applicable.

Mixture

Chemical name	Weight-%	CAS No
Sodium chloride	20 - 35	7647-14-5
Trade secret	10 - 20	-
Trade secret	1 - 2.5	-

SECTION 4: First aid measures

Description of necessary first aid measures

General advice

Contains components derived from human urine.

Inhalation

Remove to fresh air.

Eye contact

Contains human source material and / or potentially infectious components. Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a doctor.

Skin contact

Wash skin with soap and water. Wash with soap and water.

Ingestion

Call a doctor. Contains human source material and / or potentially infectious components.

Most important symptoms and effects, both acute and delayed

No information available.

For emergency responders

No information available.

Note to doctors

Contains human source material and / or potentially infectious components.

SECTION 5: Firefighting measures

Extinguishing media

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

Unsuitable extinguishing media No information available.

Specific hazards arising from the chemical No information available.

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

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions See section 8 for more information.

For emergency responders Use personal protection recommended in Section 8.

Environmental precautions See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up Do not allow into any sewer, on the ground or into any body of water. Clean contaminated surface thoroughly. Use: Disinfectant.

Precautions to prevent secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

SECTION 7: Handling and storage

Precautions for safe handling Handle in accordance with good industrial hygiene and safety practice. Follow universal and standard precautions for handling potentially infectious materials. See Section 8 for information on appropriate personal protective equipment.

Conditions for safe storage, including any incompatibilities Store according to product and label instructions.

Incompatible materials None known based on information supplied.

SECTION 8: Exposure controls/personal protection

Occupational exposure limits

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

Note See section 16 for terms and abbreviations

Biological occupational exposure limits

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

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Monitoring and observation processes

No applicable information was found.

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 Follow universal and standard precautions for handling potentially infectious materials.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

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

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	5.5-7.0	
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapour pressure	No data available	None known
Vapour density	No data available	None known
Relative density	No data available	None known
Water solubility	Soluble in water	
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known

Additional information

Explosive properties Not applicable
Oxidising properties Not applicable

SECTION 10: Stability and reactivity

Stability Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

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(M)SDS Number

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Sensitivity to mechanical impact None.
Sensitivity to static discharge None.

Conditions to avoid None known based on information supplied.

Incompatible materials None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

Acute toxicity

Numerical measures of toxicity

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

Unknown acute toxicity

7.925 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

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)	-	-

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Carcinogenicity Based on available data, the classification criteria are not met.

Reproductive toxicity Based on available data, the classification criteria are not met.

Specific target organ toxicity — single exposure Based on available data, the classification criteria are not met.

Specific target organ toxicity — repeated exposure Based on available data, the classification criteria are not met.

Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

Ecotoxicity

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

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Chemical name	Algae/aquatic plants	Fish	Crustacea
Sodium chloride	-	LC50: 4747 - 7824mg/L (96h, Oncorhynchus mykiss) LC50: 5560 - 6080mg/L (96h, Lepomis macrochirus) LC50: 6020 - 7070mg/L (96h, Pimephales promelas) LC50: 6420 - 6700mg/L (96h, Pimephales promelas) LC50: =12946mg/L (96h, Lepomis macrochirus) LC50: =7050mg/L (96h, Pimephales promelas)	EC50: 340.7 - 469.2mg/L (48h, Daphnia magna) EC50: =1000mg/L (48h, Daphnia magna)
Trade secret	EC50: =2500mg/L (72h, Desmodesmus subspicatus)	LC50: 750 - 1020mg/L (96h, Pimephales promelas) LC50: =1060mg/L (96h, Lepomis macrochirus)	EC50: =825mg/L (48h, Daphnia magna) EC50: =83mg/L (48h, Daphnia magna)

Persistence and degradability No information available.

Bioaccumulative potential There is no data for this product.

Mobility in soil No information available.

SECTION 13: Disposal considerations

Waste chemicals Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

SECTION 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

China Not regulated

Special precautions for user
Please refer to the applicable dangerous goods regulations for additional information

SECTION 15: Regulatory information

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

National regulations

Law of the People's Republic of China on Prevention and Control of Occupational Diseases

Catalogue of occupational hazard factors: Not applicable.
Catalogue of occupational diseases: Not applicable.

Regulations on the Control over Safety of Hazardous Chemicals

Product Name	Lyphochek Quantitative Urine Control, Level 2	(M)SDS Number	IRQD06063
Revision date	12-Oct-2021		

Inventory of hazardous chemicals Not applicable.

GB 18218-2009 Identification of major hazard installations for dangerous chemicals Not applicable

List of hazardous chemicals under priority management Not applicable

Regulations on Labour Protection in Workplaces Where Toxic Substances Are Used
Inventory of highly toxic goods Not applicable

Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals
List of toxic chemicals severely restricted for import and export in China Not applicable

Measures for the Environmental Management of New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances Contact supplier for inventory compliance status.

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

SECTION 16: Other information

Prepared By Bio-Rad Laboratories, Environmental Health and Safety

Revision date 12-Oct-2021

Revision Note Significant changes throughout SDS. Review all sections.

Abbreviations and acronyms

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		

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
 U.S. Environmental Protection Agency ChemView Database
 European Food Safety Authority (EFSA)
 EPA (Environmental Protection Agency)
 Acute Exposure Guideline Level(s) (AELG(s))
 U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
 U.S. Environmental Protection Agency High Production Volume Chemicals
 Food Research Journal
 Hazardous Substance Database
 International Uniform Chemical Information Database (IUCLID)
 Japan GHS Classification
 Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
 NIOSH (National Institute for Occupational Safety and Health)
 National Library of Medicine's ChemID Plus (NLM CIP)
 National Library of Medicine's PubMed database (NLM PUBMED)
 National Toxicology Program (NTP)
 New Zealand's Chemical Classification and Information Database (CCID)
 Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications
 Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme
 Organisation for Economic Co-operation and Development Screening Information Data Set
 RTECS (Registry of Toxic Effects of Chemical Substances)
 World Health Organization

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Disclaimer

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End of Safety Data Sheet