

KIT SAFETY DATA SHEET



Kit Product Name HbA2/FA1c Calibrator/Diluent Set

Kit Catalogue Number(s) 2200218

Revision date 02-Apr-2024

Kit Contents

Catalogue Number(s)	Product Name
2200119	Calibrator Diluent
2200216	D-10 Dual A2/F/A1c Level 1 Calibrator

SAFETY DATA SHEET

Revision date 28-Feb-2024

Revision Number 2.3

Section 1: Identification

Product identifier

Product Name Calibrator Diluent

Catalogue Number(s) 2200119

Other means of identification

Recommended use of the chemical and restrictions on use

Recommended use In-vitro laboratory reagent or component

Uses advised against No information available

Details of the supplier of the safety data sheet

Supplier

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

Manufacturer

Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
Hercules, California 94547
USA

Importer

Bio-Rad Laboratories Pty Ltd
189 Bush Road
Auckland
New Zealand

Technical Service +64 9 415 2280 or 0508 805 500
sales.nz@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC New Zealand: 64-98010034

Section 2: Hazard identification

GHS Classification

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

Label elements

Hazard statements

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

Other hazards which do not result in classification

No information available.

Section 3: Composition/information on ingredients

The product contains no substances which at their given concentration, are considered to be hazardous to health

Chemical name	CAS No	Weight-%
Non-hazardous ingredients	Proprietary	Balance

Section 4: First-aid measures

Description of first aid measures

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 skin with soap and water.
Ingestion	Rinse mouth.

Most important symptoms and effects, both acute and delayed

Symptoms	No information available.
Effects of Exposure	No information available.

Indication of any immediate medical attention and special treatment needed

Note to doctors	Treat symptomatically.
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Section 5: Fire-fighting 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.
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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.
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Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions	Ensure adequate ventilation.
For emergency responders	Use personal protection recommended in Section 8.

Environmental precautions

Environmental precautions	See Section 12 for additional Ecological Information.
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Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
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Methods for cleaning up Pick up and transfer to properly labelled containers.

Precautions to prevent secondary hazards

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

Section 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.

Incompatible materials None known based on information supplied.

Section 8: Exposure controls/personal protection

Control parameters

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

Biological occupational exposure limits This product, as supplied, does not contain any hazardous materials with biological 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 No special protective equipment required.

Hand protection No special protective equipment required.

Skin and body protection No special protective equipment required.

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.

Environmental exposure controls No information available.

Section 9: Physical and chemical properties

Information on basic physical and chemical properties

Physical state Liquid
Appearance aqueous solution
Colour colourless
Odour Odourless.
Odour threshold No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH		None known
Melting point / freezing point	0 °C	
Initial boiling point and boiling range	100 °C	
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability	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
Relative vapour density	No data available	None known
Relative density	No data available	None known
Water solubility	Miscible 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		None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive properties	No information available.	
Oxidising properties	No information available.	
<u>Other information</u>		
Softening point	No information available	
Molecular weight	No information available	
VOC content	No information available	
Liquid Density	No information available	
Bulk density	No information available	
Particle characteristics	No information available	

Section 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.

Section 11: Toxicological information

Acute toxicity

Information on 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

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitisation 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.

Data used to identify the health effects Refer to Section 16 for Key literature references and sources for data used to compile the SDS.

Section 12: Ecological information

Ecotoxicity

Aquatic ecotoxicity	The environmental impact of this product has not been fully investigated.
Unknown aquatic toxicity	0 % of the mixture consists of component(s) of unknown hazards to the aquatic environment.
Terrestrial ecotoxicity	There is no data for this product.
Persistence and degradability	No information available.

Bioaccumulative potential

Bioaccumulation	There is no data for this product.
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Mobility in soil

Mobility	No information available.
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Other adverse effects

No information available.

Section 13: Disposal considerations**Disposal methods**

Waste from residues/unused products	Not applicable. Not Hazardous.
Contaminated packaging	Not applicable. Not Hazardous.

Section 14: Transport information

<u>IATA</u>	Not regulated
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<u>IMDG</u>	Not regulated
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Transport in bulk according to Annex II of MARPOL and the IBC Code

No information available

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**

EPA New Zealand HSNO approval code or group standard	To be determined
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National regulations	There are no applicable tolerable exposure limits or environmental exposure limits according to the EPA Controls for Hazardous Substances
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Certified handlers, tracking and	Certified handlers are required for some substances. This includes substances requiring a
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controlled substance license requirements

controlled substance license, and most explosives, vertebrates toxic agents, and certain fumigants. Acutely toxic substances which are a Category 1 or 2, such as pesticides also require Certified handlers. Please check the Health and Safety at Work Act 2015 for further information

Tracking is required for some highly hazardous substances. These substances need to be under the control of an appropriately trained person or appropriately secured. Please check the Health and Safety at Work Act 2015 for further information

Controlled substance licenses are required to possess certain explosives, vertebrate toxic agents and fumigants. See Part 7 of the Health and Safety at Work Regulation 2017 for more information

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

NZIoC	Contact supplier for inventory compliance status.
TSCA	Contact supplier for inventory compliance status.
DSL/NDL	Contact supplier for inventory compliance status.
EINECS/ELINCS	Contact supplier for inventory compliance status.
ENCS	Contact supplier for inventory compliance status.
IECSC	Contact supplier for inventory compliance status.
KECL	Contact supplier for inventory compliance status.
PICCS	Contact supplier for inventory compliance status.
AIIC	Contact supplier for inventory compliance status.

Legend:

NZIoC - New Zealand Inventory of Chemicals

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

Section 16: Other information

Revision date 28-Feb-2024

Revision Note Reformatted and updated existing information.

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		

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)

National Institute of Technology and Evaluation (NITE)

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
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

Revision date 02-Apr-2024

Revision Number 2.2

Section 1: Identification

Product identifier

Product Name D-10 Dual A2/F/A1c Level 1 Calibrator

Catalogue Number(s) 2200216

Other means of identification

Recommended use of the chemical and restrictions on use

Recommended use In-vitro laboratory reagent or component

Uses advised against No information available

Details of the supplier of the safety data sheet

Supplier

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

Manufacturer

Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
Hercules, California 94547
USA

Importer

Bio-Rad Laboratories Pty Ltd
189 Bush Road
Auckland
New Zealand

Technical Service +64 9 415 2280 or 0508 805 500
sales.nz@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC New Zealand: 64-98010034

Section 2: Hazard identification

GHS Classification

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

Label elements

Hazard statements

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

Other hazards which do not result in classification

No information available.

Contains human source material and / or potentially infectious components

Section 3: Composition/information on ingredients

Chemical name	CAS No	Weight-%
Sucrose	57-50-1	20 - 35

Chemical name	CAS No	Weight-%
Gentamicin, sulfate (salt)	1405-41-0	0.01 - 0.099
Non-hazardous ingredients	Proprietary	Balance

Section 4: First-aid measures

Description of first aid measures

Inhalation	Remove to fresh air.
Eye contact	Contains human source material and / or potentially infectious components. Call a doctor. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Skin contact	Wash with soap and water.
Ingestion	Contains human source material and / or potentially infectious components. Call a doctor.

Most important symptoms and effects, both acute and delayed

Symptoms	No information available.
Effects of Exposure	No information available.

Indication of any immediate medical attention and special treatment needed

Note to doctors	Contains human source material and / or potentially infectious components.
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Section 5: Fire-fighting 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.
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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.
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Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions	Ensure adequate ventilation.
For emergency responders	Use personal protection recommended in Section 8.
Environmental precautions	

Environmental precautions See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Methods for containment Do not allow into any sewer, on the ground or into any body of water.

Methods for cleaning up Use: Disinfectant. Clean contaminated surface thoroughly.

Precautions to prevent secondary hazards

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

Section 7: Handling and storage

Precautions for safe handling

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

General hygiene considerations Follow universal and standard precautions for handling potentially infectious materials.

Conditions for safe storage, including any incompatibilities

Storage Conditions Store according to product and label instructions.

Incompatible materials None known based on information supplied.

Section 8: Exposure controls/personal protection

Control parameters

Exposure Limits

Chemical name	New Zealand	Australia	ACGIH TLV	United Kingdom
Sucrose 57-50-1	TWA: 10 mg/m ³	TWA: 10 mg/m ³	TWA: 10 mg/m ³	TWA: 10 mg/m ³ STEL: 20 mg/m ³

Biological occupational exposure limits This product, as supplied, does not contain any hazardous materials with biological 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).

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective clothing.

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.

Environmental exposure controls No information available.

Section 9: Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Solid
Appearance	solid
Colour	white
Odour	Odourless.
Odour threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH		None known
Melting point / freezing point	No data available	None known
Initial boiling point and boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability	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
Relative 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		None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive properties	No information available.	
Oxidising properties	No information available.	

Other information

Softening point	No information available
Molecular weight	No information available
VOC content	No information available
Liquid Density	No information available
Bulk density	No information available
Particle characteristics	No information available

Section 10: Stability and reactivity

Reactivity

Reactivity	No information available.
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Chemical stability

Stability	Stable under normal conditions.
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Explosion data

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

Possibility of hazardous reactions

Possibility of hazardous reactions	None under normal processing.
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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.

Section 11: Toxicological information

Acute toxicity

Information on 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

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Numerical measures of toxicity

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

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sucrose	= 29700 mg/kg (Rat)	-	-
Gentamicin, sulfate (salt)	> 5 g/kg (Rat)	-	-

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitisation 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.
Data used to identify the health effects	Refer to Section 16 for Key literature references and sources for data used to compile the SDS.

Section 12: Ecological information

Ecotoxicity

Aquatic ecotoxicity	The environmental impact of this product has not been fully investigated.
Unknown aquatic toxicity	0 % of the mixture consists of component(s) of unknown hazards to the aquatic environment.
Terrestrial ecotoxicity	There is no data for this product.
Persistence and degradability	No information available.

Bioaccumulative potential

Bioaccumulation	There is no data for this product.
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Mobility in soil

Mobility	No information available.
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Other adverse effects

No information available.

Section 13: Disposal considerations

Disposal methods

Waste from residues/unused products	Not applicable. Not Hazardous. Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
Contaminated packaging	Not applicable. Not Hazardous.

Section 14: Transport information

<u>IATA</u>	Not regulated
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<u>IMDG</u>	Not regulated
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Transport in bulk according to Annex II of MARPOL and the IBC Code
No information available

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

EPA New Zealand HSNO approval code or group standard To be determined

National regulations

There are no applicable tolerable exposure limits or environmental exposure limits according to the EPA Controls for Hazardous Substances

Certified handlers, tracking and controlled substance license requirements

Certified handlers are required for some substances. This includes substances requiring a controlled substance license, and most explosives, vertebrates toxic agents, and certain fumigants. Acutely toxic substances which are a Category 1 or 2, such as pesticides also require Certified handlers. Please check the Health and Safety at Work Act 2015 for further information

Tracking is required for some highly hazardous substances. These substances need to be under the control of an appropriately trained person or appropriately secured. Please check the Health and Safety at Work Act 2015 for further information

Controlled substance licenses are required to possess certain explosives, vertebrate toxic agents and fumigants. See Part 7 of the Health and Safety at Work Regulation 2017 for more information

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

NZIoC	Contact supplier for inventory compliance status.
TSCA	Contact supplier for inventory compliance status.
DSL/NDSL	Contact supplier for inventory compliance status.
EINECS/ELINCS	Contact supplier for inventory compliance status.
ENCS	Contact supplier for inventory compliance status.
IECSC	Contact supplier for inventory compliance status.
KECL	Contact supplier for inventory compliance status.
PICCS	Contact supplier for inventory compliance status.
AIIC	Contact supplier for inventory compliance status.

Legend:

NZIoC - New Zealand Inventory of Chemicals
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

Section 16: Other information

Revision date

02-Apr-2024

Revision Note

Reformatted and updated existing information.

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		

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)
 National Institute of Technology and Evaluation (NITE)
 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
 World Health Organization

Disclaimer

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End of Safety Data Sheet