KIT SAFETY DATA SHEET



Kit Product Name HbA1c Calibrator/Diluent Set

Kit Catalogue Number(s) 2200128

Revision date 02-Apr-2024

Kit Contents

Catalogue Number(s)	Product Name
2200119	Calibrator Diluent
2200126	D-10 Dual A1c Level 1 Calibrator

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SAFETY DATA SHEET

189 Bush Road

New Zealand

Albany Auckland

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

SupplierManufacturerImporterBio-Rad Laboratories Inc.Bio-Rad Laboratories, Diagnostic GroupBio-Rad Laboratories Pty Ltd

Bio-Rad Laboratories Inc.

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

Hercules, California 94547

USA USA

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.

No information available. **Effects of Exposure**

Indication of any immediate medical attention and special treatment needed

Treat symptomatically. Note to doctors

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.

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.

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 Prevent further leakage or spillage if safe to do so.

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 materialsNone known based on information supplied.

Section 8: Exposure controls/personal protection

Control parameters

Exposure LimitsThis 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 protectionNo special protective equipment required.

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

Appearanceaqueous solutionColourcolourlessOdourOdourless

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 range100 °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 No data available

limits

Lower flammability or explosive No data available

limits

Vapour pressureNo data availableNone knownRelative vapour densityNo data availableNone knownRelative densityNo data availableNone known

Water solubility
Solubility(ies)

No data available
No data available

Solubility(ies)No data availableNone knownPartition coefficientNo data availableNone knownAutoignition temperatureNo data availableNone knownDecomposition temperatureNo data availableNone knownKinematic viscosityNo data availableNone known

Dynamic viscosity

Explosive properties

Oxidising properties

No data available

No information available.

No information available.

Other information

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

Section 10: Stability and reactivity

None known

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/irritationNo 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 exposureNo 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

Section 12: Ecological information

Ecotoxicity

HRCD04157-13 - Calibrator Diluent

Revision date 28-Feb-2024

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.

Mobility in soil

Mobility No information available.

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

IMDG Not regulated

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 Certified handlers are required for some substances. This includes substances requiring a

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

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 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

189 Bush Road

New Zealand

Albany Auckland

Revision date 02-Apr-2024 Revision Number 2.2

Section 1: Identification

Product identifier

Product Name D-10 Dual A1c Level 1 Calibrator

Catalogue Number(s) 2200126

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

SupplierManufacturerImporterBio-Rad Laboratories Inc.Bio-Rad Laboratories, Diagnostic GroupBio-Rad Laboratories Pty Ltd

Bio-Rad Laboratories Inc.

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

USA USA

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	10 - 20

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Revision date 02-Apr-2024

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 doctorsContains human source material and / or potentially infectious components.

Section 5: Fire-fighting measures

Suitable Extinguishing Media

surrounding environment.

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

Unsuitable extinguishing mediaDo not scatter spilled material with high pressure water streams.

Specific hazards arising from the chemical

Specific hazards arising from the

No information available.

chemical

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.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

Environmental precautions

Revision date 02-Apr-2024

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 upUse:. 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 materialsNone 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	TWA: 10 mg/m ³			
57-50-1		-	-	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.

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 stateSolidAppearancesolidColourredOdourOdourless.

Odour threshold No information available

Property Values Remarks • Method

рΗ None known Melting point / freezing point No data available None known Initial boiling point and boiling rangeNo 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

No data available

Upper flammability or explosive No data available

Upper flammability or explosive limits

Lower flammability or explosive

limits

Vapour pressure

No data available

None known

Relative vapour density

No data available

None known

Relative vapour defisity

Relative density

No data available

None known

Water solubility

Solubile in water

No data available

None known

None known

Partition coefficient
Autoignition temperature
No data available
No data available
None known
None known
None known
None known

Kinematic viscosity

No data available

None known

No data available

None known

No data available

None known

Explosive propertiesNo information available. **Oxidising properties**No information available.

Other information

Softening point
Molecular weight
VOC content
Liquid Density
Bulk density
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

HRCD04932 - D-10 Dual A1c Level 1 Calibrator

Revision date 02-Apr-2024

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

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/irritationNo 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.

Revision date 02-Apr-2024

STOT - repeated exposureNo 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.

Mobility in soil

Mobility No information available.

Other adverse effects

No information available.

Section 13: Disposal considerations

Disposal methods

Waste from residues/unused

products

IMDG

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.

Not regulated

Section 14: Transport information

IATA Not regulated

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. Contact supplier for inventory compliance status. **TSCA 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. Contact supplier for inventory compliance status. **KECL** Contact supplier for inventory compliance status. **PICCS** 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 (time-weighted average) TWA STEL

STEL (Short Term Exposure Limit) Maximum limit value Skin designation Ceiling

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

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End of Safety Data Sheet