

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

This safety data sheet complies with the requirements of:
SS586: 2008 (2014)

Revision date 01-Feb-2024

Revision Number 2.4

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

Product identifier

Product Name Calibrator Diluent

Other means of identification

Catalogue Number(s) 2200119

Pure substance/mixture Mixture

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

Corporate Headquarters

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

For further information, please contact

Manufacturer

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

Legal Entity / Contact Address

Bio-Rad Laboratories (Singapore) PTE LTD
3A International Business Park #11-10/16
ICON@IBP
Singapore 609935

Technical Service

6424 0262
ctssingapore@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Singapore: 65-31581349

SECTION 2: Hazards identification

GHS Classification

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS): SS586: 2008 (2014)

Label elements

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS): SS586: 2008 (2014)

Other hazards which do not result in classification

SECTION 3: Composition/information on ingredients

Substance

Not applicable

Mixture

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

Non-hazardous
ingredients

Proprietary

Balance

SECTION 4: First aid measures**Description of first aid measures**

General advice	No hazards which require special 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	In the case of skin irritation or allergic reactions see a doctor. Wash skin with soap and water.
Ingestion	Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed

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

For emergency responders

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

Indication of any immediate medical attention and special treatment needed

Note to doctors	Treat symptomatically.
------------------------	------------------------

SECTION 5: Firefighting measures**Suitable 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

Specific hazards arising from the chemical	None known.
---	-------------

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.
---	---

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.

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

Reference to other sections See section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage

Precautions for safe handling

Advice on safe handling Ensure adequate ventilation.

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

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep container tightly closed in a dry and well-ventilated place.

SECTION 8: Exposure controls/personal protection

Control parameters

Occupational 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 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.

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

Other information No information available

SECTION 10: Stability and reactivityReactivity

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 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

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 related to the physical, chemical and toxicological characteristics

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

Acute toxicity**Numerical measures of toxicity**

No information available

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)		
Sodium azide	= 27 mg/kg (Rat)	= 20 mg/kg (Rabbit)	0.054 - 0.52 mg/L (Rat) 4 h

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

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.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Aspiration hazard	Classification not possible.

SECTION 12: Ecological information**Ecotoxicity**

Ecotoxicity	The environmental impact of this product has not been fully investigated.
Unknown aquatic toxicity	Contains 0 % of components with unknown hazards to the aquatic environment

Persistence and degradability

Persistence and degradability	No information available.
-------------------------------	---------------------------

Bioaccumulative potential

Bioaccumulation No information available.

Mobility

Mobility in soil No information available.

PBT and vPvB assessment No information available

Other adverse effects

Other adverse effects No information available

SECTION 13: Disposal considerations**Disposal methods**

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

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

ADR Not regulated

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

IATA Not regulated

SECTION 15: Regulatory information**Safety, health and environmental regulations/legislation specific for the substance or mixture****Singapore****Environmental Public Health Act**

Dispose of waste product or used containers according to local regulations.

Hazardous Waste (Control of Export, Import and Transit) Act

It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable regulations. Take note that wastes may be subject to export, import, or transit controls pursuant to the Basel convention and/or local regulations implementing the Basel convention.

Poison

None Listed

Workplace Safety and Health Act

Comply with the health and safety at work laws.

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

SECTION 16: Other 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

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

Label elements

Issuing Date Bio-Rad Laboratories, Environmental Health and Safety

Revision date 01-Feb-2024

Revision Note Reformatted and updated existing information.

This safety data sheet complies with the requirements of: SS586: 2008 (2014)

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 complies with the requirements of:
SS586: 2008 (2014)

Revision date 02-Apr-2024

Revision Number 2.2

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

Product identifier

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

Other means of identification

Catalogue Number(s) 2200216

Pure substance/mixture Mixture

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

Corporate Headquarters

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

For further information, please contact

Manufacturer

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

Legal Entity / Contact Address

Bio-Rad Laboratories (Singapore) PTE LTD
3A International Business Park #11-10/16
ICON@IBP
Singapore 609935

Technical Service

6424 0262
ctssingapore@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Singapore: 65-31581349

SECTION 2: Hazards identification

GHS Classification

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS): SS586: 2008 (2014)

Label elements

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS): SS586: 2008 (2014)
Contains Gentamicin, sulfate (salt) May produce an allergic reaction

Other hazards which do not result in classification

SECTION 3: Composition/information on ingredients

Substance

Not applicable

Mixture

Chemical name	EC No (EU Index No)	CAS No	Weight-%
Sucrose	200-334-9	57-50-1	20 - 35

Non-hazardous
ingredients

Proprietary

Balance

SECTION 4: First aid measures**Description of first aid measures**

General advice	No hazards which require special first aid measures.
Inhalation	Remove to fresh air.
Eye contact	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	Call a doctor.

Most important symptoms and effects, both acute and delayed

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

For emergency responders

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

Indication of any immediate medical attention and special treatment needed

Note to doctors	Treat symptomatically.
------------------------	------------------------

SECTION 5: Firefighting measures**Suitable 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

Specific hazards arising from the chemical	None known.
---	-------------

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.
---	---

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 Clean contaminated surface thoroughly.

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

Reference to other sections See section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage**Precautions for safe handling**

Advice on safe handling Ensure adequate ventilation.

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

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep container tightly closed in a dry and well-ventilated place.

SECTION 8: Exposure controls/personal protection**Control parameters****Occupational exposure limits**

Chemical name	Singapore	ACGIH TLV
Sucrose 57-50-1	PEL: 10 mg/m ³	TWA: 10 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).

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.

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

Other information 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 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

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 related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Acute toxicity

Numerical measures of toxicity

No information available

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)		
Water	> 90 mL/kg (Rat)		
Tobramycin	> 7500 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	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.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Aspiration hazard	Classification not possible.

SECTION 12: Ecological information

Ecotoxicity

Ecotoxicity	The environmental impact of this product has not been fully investigated.
Unknown aquatic toxicity	Contains 0 % of components with unknown hazards to the aquatic environment

Persistence and degradability

Persistence and degradability	No information available.
--------------------------------------	---------------------------

Bioaccumulative potential

Bioaccumulation	No information available.
------------------------	---------------------------

Mobility

Mobility in soil	No information available.
PBT and vPvB assessment	No information available

Other adverse effects

Other adverse effects	No information available
------------------------------	--------------------------

SECTION 13: Disposal considerations**Disposal methods**

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

SECTION 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

SECTION 15: Regulatory information**Safety, health and environmental regulations/legislation specific for the substance or mixture****Singapore**

Environmental Public Health Act
Dispose of waste product or used containers according to local regulations.

Hazardous Waste (Control of Export, Import and Transit) Act
It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine

the proper waste identification and disposal methods in compliance with applicable regulations. Take note that wastes may be subject to export, import, or transit controls pursuant to the Basel convention and/or local regulations implementing the Basel convention.

Poison

None Listed

Workplace Safety and Health Act

See section 8 for national exposure control parameters. Comply with the health and safety at work laws.

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

SECTION 16: Other 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

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

Label elements

Issuing Date Bio-Rad Laboratories, Environmental Health and Safety

Revision date 02-Apr-2024

Revision Note Reformatted and updated existing information.

This safety data sheet complies with the requirements of: SS586: 2008 (2014)

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