KIT SAFETY DATA SHEET



Kit Product Name HbA2/FA1c Calibrator/Diluent Set

Kit Catalog Number(s) 2200218

Revision date 02-Apr-2024

Kit Contents

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

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SAFETY DATA SHEET



Revision date 01-Feb-2024 **Revision Number** 2.2

1. Identification

Product identifier

Product Name Calibrator Diluent

Other means of identification

2200119 Catalog Number(s)

Recommended use of the chemical and restrictions on use

Recommended use In-vitro laboratory reagent or component

Details of the supplier of the safety data sheet

Corporate Headquarters Manufacturer Address

Bio-Rad Laboratories, Diagnostic Group Bio-Rad Laboratories Inc. 1000 Alfred Nobel Drive 4000 Alfred Nobel Drive Hercules, CA 94547 Hercules, California 94547

USA

Bio-Rad Laboratories

Clinical Diagnostics 4000 Alfred Nobel Drive Hercules, California 94547

Legal Entity / Contact Address

USA

Technical Service 1-800-224-6723

TechSupport.USSD@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC USA: 1 (800) 424-9300

2. Hazard(s) identification

Classification

USA

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Hazard statements

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

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

Odor Odorless **Appearance** aqueous solution Physical state Liquid

Other information

No information available.

Calibrator Diluent Revision date 01-Feb-2024

3. Composition/information on ingredients

Substance

Not applicable.

<u>Mixture</u>

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

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 physician.

Skin contact Wash skin with soap and water.

Ingestion Rinse mouth.

Most important symptoms and effects, both acute and delayed

Symptoms No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. Fire-fighting measures

surrounding environment.

Specific hazards arising from the

chemical

No information available.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

^{*}The exact percentage (concentration) of composition has been withheld as a trade secret.

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 labeled containers.

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

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.

Appropriate engineering controls

Engineering controls Showers

Eyewash stations Ventilation systems.

Individual protection measures, such as personal protective equipment

Eve/face protection No special protective equipment required.

Skin and body protectionNo 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.

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

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Liquid

Appearance aqueous solution colorless
Odor Odorless

Odor threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

H None known

Melting point / freezing point 0 °C / 32 °F

None known

Initial boiling point and boiling range100 °C / 212 °F No data available Flash point

None known **Evaporation rate** No data available None known **Flammability** No data available None known None known

No data available

Flammability Limit in Air

Upper flammability or explosive

limits

Lower flammability or explosive No data available

limits

No data available Vapor pressure Relative vapor density No data available Relative density No data available Miscible in water

Water solubility

Solubility(ies) No data available **Partition coefficient** No data available Autoignition temperature No data available **Decomposition temperature** No data available Kinematic viscosity No data available **Dynamic viscosity** No data available

Other information

No information available **Explosive properties Oxidizing properties** No information available Softening point No information available Molecular weight No information available No information available **VOC** content **Liquid Density** No information available **Bulk density** No information available

10. Stability and reactivity

No information available. Reactivity

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid None known based on information supplied.

None known based on information supplied. Incompatible materials

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

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

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

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

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 sensitization No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposureNo information available.

Aspiration hazard No information available.

Other adverse effects No information available.

Interactive effects No information available.

12. Ecological information

Ecotoxicity The environmental impact of this product has not been fully investigated.

Persistence and degradability No information available.

Bioaccumulation There is no data for this product.

Other adverse effects No information available.

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.

14. Transport information

DOT Not regulated

TDG Not regulated

MEX Not regulated

IATA Not regulated

IMDG Not regulated

15. Regulatory information

International Inventories Contact supplier for inventory compliance status

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Water	-	-	X
7732-18-5			
Sodium azide	X	X	X
26628-22-8			

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA Health hazards 0 Flammability 0 Instability 0 Special hazards - HMIS Health hazards 0 Flammability 0 Physical hazards 0 Personal protection X

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)

National Institute of Technology and Evaluation (NITE)

Australia 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)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications

Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

World Health Organization

Revision date 01-Feb-2024

Revision Note Reformatted and updated existing information.

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



Legal Entity / Contact Address

Bio-Rad Laboratories

4000 Alfred Nobel Drive

Hercules, California 94547

Clinical Diagnostics

USA

Revision date 02-Apr-2024 Revision Number 2.2

1. Identification

Product identifier

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

Other means of identification

Catalog Number(s) 2200216

Recommended use of the chemical and restrictions on use

Recommended use In-vitro laboratory reagent or component

Details of the supplier of the safety data sheet

<u>Corporate Headquarters</u> <u>Manufacturer Address</u>

Bio-Rad Laboratories Inc.

Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive

Hercules, CA 94547

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

USA USA

Technical Service 1-800-224-6723

TechSupport.USSD@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC USA: 1 (800) 424-9300

2. Hazard(s) identification

Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Hazard statements

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

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

Appearance solid Physical state Solid Odor Odorless

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Other information

No information available.

Contains human source material and / or potentially infectious components

3. Composition/information on ingredients

Substance

Not applicable.

Mixture

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

^{*}The exact percentage (concentration) of composition has been withheld as a trade secret.

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

physician. 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

physician.

Most important symptoms and effects, both acute and delayed

Symptoms No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians Contains human source material and / or potentially infectious components.

5. Fire-fighting measures

surrounding environment.

Specific hazards arising from the

chemical

No information available.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Use personal protection equipment.

Revision date 02-Apr-2024

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

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.

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 Store according to product and label instructions.

8. Exposure controls/personal protection

Control parameters

Exposure Limits

Chemical name	ACGIH TLV	OSHA PEL	NIOSH
Sucrose	TWA: 10 mg/m ³	TWA: 15 mg/m³ total dust	TWA: 10 mg/m³ total dust
57-50-1	-	TWA: 5 mg/m³ respirable	TWA: 5 mg/m ³ respirable dust
		fraction	-
		(vacated) TWA: 15 mg/m³ total	
		dust	
		(vacated) TWA: 5 mg/m ³	
		respirable fraction	

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 protectionWear suitable protective clothing.

exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations

Follow universal and standard precautions for handling potentially infectious materials.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid
Appearance solid
Color white
Odor Odorless

Odor 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

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Vapor pressureNo data availableNone knownRelative vapor densityNo data availableNone knownRelative densityNo data availableNone 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 No data available Dynamic viscosity None known

Other information

Explosive properties

Oxidizing properties

Softening point

Molecular weight

VOC content

Liquid Density

No information available

10. Stability and reactivity

Reactivity No information available.

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions
None under normal processing.

Conditions to avoid None known based on information supplied.

Incompatible materialsNone known based on information supplied.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

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

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)	-	-
57-50-1			

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 sensitization No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Target organ effects Respiratory system, Eyes.

Aspiration hazard No information available.

Other adverse effects No information available.

Interactive effects No information available.

12. Ecological information

Ecotoxicity The environmental impact of this product has not been fully investigated.

Revision date 02-Apr-2024

Persistence and degradability No information available.

Bioaccumulation There is no data for this product.

Other adverse effects No information available.

13. Disposal considerations

Disposal methods

Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

Contaminated packaging Do not reuse empty containers.

14. Transport information

DOT Not regulated

TDG Not regulated

MEX Not regulated

IATA Not regulated

IMDG Not regulated

15. Regulatory information

<u>International Inventories</u> Contact supplier for inventory compliance status

US Federal Regulations

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US State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals:.

Chemical name	California Proposition 65	
Tobramycin - 32986-56-4	Developmental	
Gentamicin, sulfate (salt) - 1405-41-0	Developmental	

U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Sucrose 57-50-1	-	X	X
Water 7732-18-5	-	-	X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

	inform	IGLIOII

NFPA_ Health hazards 0 Flammability 0 Instability 0 Special hazards -Health hazards 0 Flammability 0 Physical hazards 0 Personal protection X HMIS

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)

Ceiling Maximum limit value Skin designation

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

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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

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Food Research Journal

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National Toxicology Program (NTP)

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Revision date 02-Apr-2024

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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