



SAFETY DATA SHEET

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

Revision date 01-May-2023

Revision Number 2.2

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

Product identifier

Product Name Variant II Hemoglobin A1c Calibrator 2

Other means of identification

Catalogue Number(s) 2702108NU

Pure substance/mixture Mixture

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic

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
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Legal Entity / Contact Address

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Technical Service

6424 0262
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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)

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-%
Human Source Material	-	NO-CAS-20	50 - 100
Sucrose	200-334-9	57-50-1	10 - 20
Water	231-791-2	7732-18-5	1 - 2.5
Tobramycin	251-322-5	32986-56-4	0.01 - 0.099
Gentamicin, sulfate (salt)	215-778-9	1405-41-0	0.01 - 0.099
Glycine, N,N-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate	-	6381-92-6	< 0.001

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	Wash skin with soap and water.
Ingestion	Call a doctor.

Most important symptoms and effects, both acute and delayed

Symptoms	No information available.
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For emergency responders

Self-protection of the first aider	No information available.
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Indication of any immediate medical attention and special treatment needed

Note to doctors	Treat symptomatically.
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SECTION 5: Firefighting measures

Suitable Extinguishing Media

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

Specific hazards arising from the	None known.
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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. 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	Varies
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
Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapour pressure	No data available	None known
Vapour density	No data available	None known
Relative density	No data available	None known
Water solubility	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
<u>Other information</u>	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** 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****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.
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Bioaccumulative potential

Bioaccumulation	No information available.
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Mobility

Mobility in soil	No information available.
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PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
Glycine, N,N-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate	The substance is not PBT / vPvB

Other adverse effects

Other adverse effects	No information available
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SECTION 13: Disposal considerations

Waste treatment 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

Chemical name	Poison	Poison Schedule Number
Tobramycin	X	First schedule Third schedule

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

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Revision Note SDS sections updated, 1, 2, 3.

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Disclaimer

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End of Safety Data Sheet