

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 was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 28-Feb-2024

Revision Number 2.3

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

1.1. Product identifier

Product Name	Calibrator Diluent
Catalogue Number(s)	2200119
Nanoforms	Not applicable
Pure substance/mixture	Mixture

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended use	In-vitro laboratory reagent or component
Uses advised against	No information available

1.3. Details of the supplier of the safety data sheet

Corporate Headquarters

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

Manufacturer

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

Legal Entity / Contact Address

The Junction
Station Road
Watford, WD17 1ET
UK

Bio-Rad Laboratories Pvt. Ltd.
Bio-Rad House
86-87, Udyog Vihar Phase IV Gurgaon
122005
Haryana India

Bio-Rad Laboratories (Pty) Ltd.
43 Bolton Road
Parkwood, Johannesburg 2192
South Africa

EU Representative:
Bio-Rad
3 bld Raymond Poincaré
92430 Marnes-la-Coquette
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Phone: (33) 1-4795-6000

For further information, please contact

Technical Service

00800 00246 723
Ireland: Techsupport.UK@bio-rad.com
India: support.india@bio-rad.com
South Africa: cdg_techsupport_eemea@bio-rad.com

1.4. Emergency telephone number

24 Hour Emergency Phone Number	CHEMTREC Ireland: 353-19014670 CHEMTREC India: 000-800-100-7141 CHEMTREC South Africa: 0-800-983-611
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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.2. Label elements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

Hazard statements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.3. Other hazards

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

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

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

No information available

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. 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	In the case of skin irritation or allergic reactions see a doctor. Wash skin with soap and water.
Ingestion	Rinse mouth.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms	No information available.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to doctors	Treat symptomatically.
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SECTION 5: Firefighting measures

5.1. 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.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical No information available.

5.3. Advice for firefighters

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

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. 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 Take up mechanically, placing in appropriate containers for disposal.

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

6.4. Reference to other sections

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

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling Ensure adequate ventilation.

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

7.2. Conditions for safe storage, including any incompatibilities

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

7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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

Biological occupational exposure limits

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

Derived No Effect Level (DNEL) No information available.
Predicted No Effect Concentration (PNEC)

8.2. Exposure controls

Personal protective equipment

Eye/face protection No special protective equipment required.

Skin and body protection No special protective equipment required.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

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

Environmental exposure controls No information available.

SECTION 9: Physical and chemical properties

9.1. 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>
Melting point / freezing point	0 °C	
Initial boiling point and boiling range	100 °C	
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	
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
pH	No data available	None known

pH (as aqueous solution)	No data available	No information available
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	Miscible in water	
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Vapour pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Relative vapour density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

9.2. Other information**9.2.1. Information with regards to physical hazard classes**

Not applicable

9.2.2. Other safety characteristics

No information available

SECTION 10: Stability and reactivity**10.1. Reactivity**

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials None known based on information supplied.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008****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

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

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitisation No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

11.2. Information on other hazards**11.2.1. Endocrine disrupting properties**

Endocrine disrupting properties This product does not contain any known or suspected endocrine disruptors.

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information**12.1. Toxicity**

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.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation There is no data for this product.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. 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

IATA

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	None

IMDG

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	None
14.7 Maritime transport in bulk according to IMO instruments	No information available

RID

14.1 UN number	Not regulated
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14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	None

ADR

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	None

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****National regulations****Germany**

Water hazard class (WGK) non-hazardous to water (nwg)

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

International Inventories

Contact supplier for inventory compliance status

15.2. Chemical safety assessment**Chemical Safety Report**

No information available

SECTION 16: Other information**Key or legend to abbreviations and acronyms used in the safety data sheet****Legend**

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

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)
 European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA_RAC)
 European Chemicals Agency (ECHA) (ECHA_API)
 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

Revision Note Reformatted and updated existing information.

Revision date 28-Feb-2024

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

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 was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 02-Apr-2024

Revision Number 2.2

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

1.1. Product identifier

Product Name D-10 Dual A2/F/A1c Level 1 Calibrator
Catalogue Number(s) 2200216
Nanoforms Not applicable
Pure substance/mixture Mixture

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended use In-vitro laboratory reagent or component
Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Corporate Headquarters

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

Manufacturer

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

Legal Entity / Contact Address

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Bio-Rad Laboratories (Pty) Ltd.
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South Africa

EU Representative:
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3 bld Raymond Poincaré
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Phone: (33) 1-4795-6000

For further information, please contact

Technical Service

00800 00246 723
Ireland: Techsupport.UK@bio-rad.com
India: support.india@bio-rad.com
South Africa: cdg_techsupport_eemea@bio-rad.com

1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Ireland: 353-19014670
CHEMTREC India: 000-800-100-7141
CHEMTREC South Africa: 0-800-983-611

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.2. Label elements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

Hazard statements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

EUH208 - Contains Gentamicin, sulfate (salt) May produce an allergic reaction.

2.3. Other hazards

Contains human source material and / or potentially infectious components

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sucrose 57-50-1	20 - 35	Not available	200-334-9	Not classified	-	-	-
Gentamicin, sulfate (salt) 1405-41-0	0.01 - 0.099	Not available	215-778-9	Resp. Sens. 1 (H334) Skin Sens. 1 (H317)	Skin Sens. 1 :: C>=0.1% Resp. Sens. 1 :: C>=0.1%	-	-

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Sucrose 57-50-1	29700	No data available	No data available	No data available	No data available
Gentamicin, sulfate (salt) 1405-41-0	5000	No data available	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. 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.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms	No information available.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to doctors	Contains human source material and / or potentially infectious components.
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
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Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
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Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
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5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	No information available.
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5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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

6.2. Environmental precautions

Environmental precautions	See Section 12 for additional Ecological Information.
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6.3. 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.
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

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

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling Ensure adequate ventilation.

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

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store according to product and label instructions.

7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

Chemical name	European Union	Austria	Belgium	Bulgaria	Croatia
Sucrose 57-50-1	-	-	TWA: 10 mg/m ³	TWA: 10.0 mg/m ³	TWA: 10 mg/m ³ STEL: 20 mg/m ³
Chemical name	Cyprus	Czech Republic	Denmark	Estonia	Finland
Sucrose 57-50-1	-	-	-	TWA: 10 mg/m ³	-
Chemical name	France	Germany TRGS	Germany DFG	Greece	Hungary
Sucrose 57-50-1	TWA: 10 mg/m ³	-	-	-	-
Chemical name	Ireland	Italy MDLPS	Italy AIDII	Latvia	Lithuania
Sucrose 57-50-1	TWA: 10 mg/m ³ STEL: 20 mg/m ³	-	TWA: 10 mg/m ³	TWA: 5 mg/m ³	TWA: 10 mg/m ³
Chemical name	Portugal	Romania	Slovakia	Slovenia	Spain
Sucrose 57-50-1	TWA: 10 mg/m ³	-	-	-	TWA: 10 mg/m ³
Chemical name	Sweden	Switzerland	United Kingdom		
Sucrose 57-50-1	-	-	TWA: 10 mg/m ³ STEL: 20 mg/m ³		

Biological occupational exposure limits

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

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Hand protection	Wear suitable gloves.
Skin and body protection	Wear suitable protective clothing.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Follow universal and standard precautions for handling potentially infectious materials.
Environmental exposure controls	No information available.

SECTION 9: Physical and chemical properties

9.1. 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>
Melting point / freezing point	No data available	None known
Initial boiling point and boiling range	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	
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
pH	No data available	None known
pH (as aqueous solution)	No data available	No information available
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	Soluble in water	
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Vapour pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Relative vapour density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

9.2. Other information

9.2.1. Information with regards to physical hazard classes

Not applicable

9.2.2. Other safety characteristics

No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials None known based on information supplied.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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)	-	-
Gentamicin, sulfate (salt)	> 5 g/kg (Rat)	-	-

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

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitisation No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties This product does not contain any known or suspected endocrine disruptors.

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

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.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation There is no data for this product.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations**13.1. Waste treatment 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.

SECTION 14: Transport information**IATA**

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	None

IMDG

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	None
14.7 Maritime transport in bulk according to IMO instruments	No information available

RID

14.1 UN number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	None

ADR

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	None

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**National regulations****Germany**

Water hazard class (WGK) slightly hazardous to water (WGK 1)

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

EU - Plant Protection Products (1107/2009/EC)

Chemical name	EU - Plant Protection Products (1107/2009/EC)
Sucrose - 57-50-1	Plant protection agent

International Inventories

Contact supplier for inventory compliance status

15.2. Chemical safety assessment**Chemical Safety Report**

No information available

SECTION 16: Other information**Key or legend to abbreviations and acronyms used in the safety data sheet****Full text of H-Statements referred to under section 3**

H317 - May cause an allergic skin reaction

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average)
Ceiling Maximum limit value

STEL
*

STEL (Short Term Exposure Limit)
Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method

Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

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)
European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA_RAC)
European Chemicals Agency (ECHA) (ECHA_API)
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

Revision Note Reformatted and updated existing information.

Revision date 02-Apr-2024

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer

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End of Safety Data Sheet