# KIT SAFETY DATA SHEET



Kit Product Name Variant II HbA2 /HbA1c Dual Prog Reorder Pack

Kit Catalogue Number(s) 2702500

Revision date 08-Oct-2021

## **Kit Contents**

Catalogue Number(s)	Product Name
2700351, 2700352, 2700350	Whole Blood Primer
2200119	Calibrator Diluent
2702501	Variant II Dual Buffer 1
2702502	Variant II Dual Buffer 2
2702503	Variant II Dual Wash/Diluent
2702508	Variant II Dual Analytical Cartridge
2702505	Variant II Dual B-Thal Calibrator Level 1
2702506	Variant II Dual B-Thal Calibrator Level 2
2702512	Variant II Dual HbA1c Calibrator Level 1
2702513	Variant II Dual HbA1c Calibrator Level 2

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# SAFETY DATA SHEET

**Legal Entity / Contact Address** 

Bio-Rad Laboratories Ltd

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

**Revision date Previous** Revision Number 1.4 21-Sep-2021 27-Aug-2021

revision date

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

1.1. Product identifier

**Product Name** Whole Blood Primer

2700351, 2700352, 2700350 Catalogue Number(s)

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** Manufacturer

Bio-Rad Laboratories Inc. Bio-Rad Laboratories, Diagnostic Group 1000 Alfred Nobel Drive 4000 Alfred Nobel Drive

Hercules, CA 94547 Hercules, California 94547

USA USA

The Junction

Station Road Watford, WD17 1ET

UK

For further information, please contact

00800 00246 723 **Technical Service** 

Techsupport.UK@bio-rad.com

1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

### **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

Contains human source material and / or potentially infectious components

## **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Not applicable

3.2 Mixtures

#### 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 >=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 physician. Contains human source material and / or potentially infectious

components.

**Skin contact** Wash skin with soap and water.

Ingestion Call a physician. Contains human source material and / or potentially infectious

components.

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

**Symptoms** No information available.

4.3. Indication of any immediate medical attention and special treatment needed

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

## **SECTION 5: Firefighting measures**

5.1. Extinguishing media

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.

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** Do not allow into any sewer, on the ground or into any body of water.

Methods for cleaning up Clean contaminated surface thoroughly. Use:. Disinfectant.

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

#### 7.3. Specific end use(s)

Identified uses

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)
Predicted No Effect Concentration
(PNEC)

No information available. No information available.

(-----/

8.2. Exposure controls

Whole Blood Primer Revision date 21-Sep-2021

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.

No protective equipment is needed under normal use conditions. If exposure limits are Respiratory protection

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

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

**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 red Odour Odourless.

**Odour threshold** No information available

Values Remarks • Method Property

No data available Melting point / freezing point None known Boiling point / boiling range No data available None known Flammability (solid, gas) 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

Flash point No data available None known **Autoignition temperature** No data available None known **Decomposition temperature** None known

None known

None known

No data available No information available pH (as aqueous solution) None known

Kinematic viscosity No data available **Dynamic viscosity** No data available

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 No data available Relative density None known

No data available **Bulk density Liquid Density** No data available

No data available None known Vapour density

Particle characteristics

No information available **Particle Size** Particle Size Distribution No information available

#### 9.2. Other information

## 9.2.1. Information with regard 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

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 sensitization** No information available.

Revision date 21-Sep-2021

**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** No information available.

11.2.2. Other information

Other adverse effects No information available.

## **SECTION 12: Ecological information**

12.1. Toxicity

**Ecotoxicity** 

**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

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 numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

#### IMDG

14.1 UN number or ID numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

14.7 Maritime transport in bulk No information available according to IMO instruments

#### RID

14.1 UN number
14.2 UN proper shipping name
14.3 Transport hazard class(es)
14.4 Packing group
14.5 Environmental hazards
Not regulated
Not regulated
Not regulated
Not applicable

14.6 Special Precautions for Users

Special Provisions None

#### ADR

14.1UN number or ID numberNot regulated14.2UN proper shipping nameNot regulated14.3Transport hazard class(es)Not regulated14.4Packing groupNot regulated14.5Environmental hazardsNot 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.

#### Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (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

<u>International Inventories</u> 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 SDS sections updated 2

Revision date 21-Sep-2021

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 17-Aug-2021 Previous 17-Aug-2021 Revision Number 2

revision date

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

#### 1.1. Product identifier

Product Name Calibrator Diluent

Catalogue Number(s) 2200119

**EC No** 231-791-2

**CAS No** 7732-18-5

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

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

Bio-Rad Laboratories Inc.

Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
4000 Alfred Nobel Drive

Hercules, CA 94547 Hercules, California 94547

USA USA

**Legal Entity / Contact Address** 

Bio-Rad Laboratories Ltd

The Junction Station Road Watford, WD17 1ET

UK

For further information, please contact

**Technical Service** 00800 00246 723

Techsupport.UK@bio-rad.com

#### 1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

## **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

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 >=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 physician.

**Skin contact** Wash skin with soap and water. In the case of skin irritation or allergic reactions see a

physician.

**Ingestion** Rinse mouth.

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

**Symptoms** No information available.

4.3. Indication of any immediate medical attention and special treatment needed

## **SECTION 5: Firefighting measures**

5.1. Extinguishing media

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.

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** Store according to product and label instructions.

7.3. Specific end use(s)

**Identified uses** 

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)
Predicted No Effect Concentration
(PNEC)

No information available. No information available.

8.2. Exposure controls

Personal protective equipment

No special protective equipment required. Eye/face protection

Skin and body protection No special protective equipment required.

No protective equipment is needed under normal use conditions. If exposure limits are Respiratory protection

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

None known

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

**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

**Property** Remarks • Method Values

Melting point / freezing point 0 °C

100 °C Boiling point / boiling range

Flammability (solid, gas) No data available None known None known

Flammability Limit in Air

Upper flammability or explosive No data available limits

Lower flammability or explosive No data available

limits

No data available Flash point

**Autoignition temperature** No data available None known **Decomposition temperature** None known

None known pН

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 No data available Partition coefficient None known

No data available Vapour pressure None known Relative density No data available None known

No data available **Bulk density Liquid Density** No data available

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 regard 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 Avoid contact with metals. This product contains Sodium azide. Sodium azide can react

with Copper, Brass, Lead, and solder in piping systems to form explosive compounds and

toxic gases.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials Metals. Metals.

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

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 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.

**Aspiration hazard** No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

11.2.2. Other information

Other adverse effects No information available.

## **SECTION 12: Ecological information**

12.1. Toxicity

**Ecotoxicity** 

**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

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

Flush pipes with water frequently if discarding solutions containing Sodium azide into metal piping systems. Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation. 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 numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

#### **IMDG**

14.1 UN number or ID numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

14.7 Maritime transport in bulk No information available according to IMO instruments

#### RID

14.1 UN numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

#### ADR

14.1UN number or ID numberNot regulated14.2UN proper shipping nameNot regulated14.3Transport hazard class(es)Not regulated14.4Packing groupNot regulated14.5Environmental hazardsNot 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.

#### Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (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

<u>International Inventories</u> 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

Calibrator Diluent Revision date 17-Aug-2021

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 SDS sections updated 1 2 3

Revision date 17-Aug-2021

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 27-Aug-2021 Previous 23-Nov-2020 Revision Number 2.2

revision date

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

1.1. Product identifier

Product Name Variant II Dual Buffer 1

Catalogue Number(s) 2702501

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

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

Bio-Rad Laboratories Inc.

Bio-Rad Laboratories, Diagnostic Group

4000 Alfred Nobel Drive

4000 Alfred Nobel Drive

Hercules, CA 94547 Hercules, California 94547

USA USA

Legal Entity / Contact Address

Bio-Rad Laboratories Ltd

The Junction Station Road Watford, WD17 1ET

UK

For further information, please contact

**Technical Service** 00800 00246 723

Techsupport.UK@bio-rad.com

1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

### **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

Chemical name	Weight-%	REACH registration number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water 7732-18-5	50 - 100	No data available	231-791-2	No data available	-	-	-
Phosphoric acid, monosodium salt, monohydrate 10049-21-5	0.3 - 0.999	No data available	-	No data available	-	-	-
Sodium phosphate dibasic 7558-79-4	0.1 - 0.299	No data available	231-448-7	No data available	-	-	-
1,3-Propanediol, 2-[bis(2-hydroxyethy I)amino]-2-(hydroxy methyl)- 6976-37-0	0.01 - 0.099	No data available	230-237-7	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) STOT SE 3 (H335)	-	-	-
Sodium azide 26628-22-8	0.01 - 0.099	No data available	247-852-1	Acute Tox. 2 (H300) (EUH032) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	-	-	-

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 >=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 physician.

**Skin contact** Wash skin with soap and water. In the case of skin irritation or allergic reactions see a

physician.

**Ingestion** Rinse mouth.

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

**Symptoms** No information available.

### 4.3. Indication of any immediate medical attention and special treatment needed

**Note to physicians** Treat symptomatically.

## **SECTION 5: Firefighting measures**

5.1. Extinguishing media

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.

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** Store according to product and label instructions.

7.3. Specific end use(s)

**Identified uses** 

-

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.

Chemical name	European Union	Austria	Belgium	Bu	Igaria	Croatia
Sodium azide	TWA: 0.1 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup>	-		0.3 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup>
26628-22-8	STEL: 0.3 mg/m <sup>3</sup>	STEL 0.3 mg/m <sup>3</sup>		TWA: (	0.1 mg/m <sup>3</sup>	STEL: 0.3 mg/m <sup>3</sup>
	*	H*			K*	K*
Chemical name	Cyprus	Czech Republic	Denmark	_~	stonia	Finland
Sodium azide	-	-	TWA: 0.1 mg/m <sup>3</sup>		0.1 mg/m³	TWA: 0.1 mg/m <sup>3</sup>
26628-22-8			H*		0.3 mg/m <sup>3</sup>	STEL: 0.3 mg/m <sup>3</sup>
	_	_			A*	iho*
Chemical name	France	Germany	Germany MAK	Gı	eece	Hungary
Sodium azide	TWA: 0.1 mg/m <sup>3</sup>	TWA: 0.2 mg/m <sup>3</sup>	TWA: 0.2 mg/m <sup>3</sup>		-	TWA: 0.1 mg/m <sup>3</sup>
26628-22-8	STEL: 0.3 mg/m <sup>3</sup>		Ceiling / Peak: 0.4			STEL: 0.3 mg/m <sup>3</sup>
	*		mg/m³			
Chemical name	Ireland	Italy	Italy REL	_	atvia	Lithuania
Sodium azide	TWA: 0.1 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup>	-		0.1 mg/m <sup>3</sup>	-
26628-22-8	STEL: 0.3 mg/m <sup>3</sup>	STEL: 0.3 mg/m <sup>3</sup>		STEL:	0.3 mg/m <sup>3</sup>	
	Sk*	pelle*			*	
Chemical name	Luxembourg	Malta	Netherlands		orway	Poland
Sodium azide	-	-	TWA: 0.1 mg/m <sup>3</sup>			STEL: 0.3 mg/m <sup>3</sup>
26628-22-8			STEL: 0.3 mg/m <sup>3</sup>	STEL:	STEL: 0.3 mg/m <sup>3</sup> TWA: 0.1 mg/n	
			H*	-		
Chemical name	Portugal	Romania	Slovakia		venia	Spain
Sodium azide	TWA: 0.1 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup>		0.1 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup>
26628-22-8	STEL: 0.3 mg/m <sup>3</sup>	STEL: 0.3 mg/m <sup>3</sup>	K*		TEL mg/m <sup>3</sup>	STEL: 0.3 mg/m <sup>3</sup>
	Ceiling: 0.29 mg/m <sup>3</sup>	P*			K*	vía dérmica*
	Ceiling: 0.11 ppm					
	P*					
Chemical name	Sı	weden	Switzerland	2		ted Kingdom
Sodium azide		-	TWA: 0.2 mg/m			A: 0.1 mg/m <sup>3</sup>
26628-22-8			STEL: 0.4 mg/m³ STEL: 0.3 mg			
					l	Sk*

#### **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)
Predicted No Effect Concentration
(PNEC)

No information available. No information available.

8.2. Exposure controls

Personal protective equipment

**Eye/face protection** No special protective equipment required.

**Skin and body protection**No special protective equipment required.

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

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

No information available. **Environmental exposure controls** 

## SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state Liquid Colour colourless Odour Odourless.

**Odour threshold** No information available

**Property** Values Remarks • Method

Melting point / freezing point 0 °C 100 °C Boiling point / boiling range

Flammability (solid, gas) 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

Flash point No data available None known **Autoignition temperature** No data available None known **Decomposition temperature** 

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

Miscible in water Water solubility

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

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 regard 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

Stable under normal conditions. Stability

**Explosion data** 

Sensitivity to mechanical impact None. Sensitivity to static discharge

#### 10.3. Possibility of hazardous reactions

**Possibility of hazardous reactions** Avoid contact with metals. This product contains Sodium azide. Sodium azide can react

with Copper, Brass, Lead, and solder in piping systems to form explosive compounds and

toxic gases.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials Metals.

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** 

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
Sodium phosphate dibasic	= 17 g/kg (Rat)	-	-
Sodium azide	= 27 mg/kg (Rat)	= 20 mg/kg (Rabbit)	-
		= 50 mg/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 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.

**Aspiration hazard** No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

11.2.2. Other information

Other adverse effects No information available.

## **SECTION 12: Ecological information**

#### 12.1. Toxicity

## Ecotoxicity

**Unknown aquatic toxicity**Contains 0 % of components with unknown hazards to the aquatic environment.

Chemical name	Algae/aquatic plants	Fish	Toxicity to	Crustacea
			microorganisms	
Sodium azide	-	LC50: =0.7mg/L (96h,	-	-
		Lepomis macrochirus)		
		LC50: =0.8mg/L (96h,		
		Oncorhynchus mykiss)		
		LC50: =5.46mg/L (96h,		
		Pimephales promelas)		

## 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

Chemical name	PBT and vPvB assessment
Sodium phosphate dibasic	PBT assessment does not apply

1,3-Propanediol, 2-[bis(2-hydroxyethyl)amino]-2-(hydroxymethyl)-	The substance is not PBT / vPvB
Sodium azide	PBT assessment does not apply

#### 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

Flush pipes with water frequently if discarding solutions containing Sodium azide into metal piping systems. 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
14.2 UN proper shipping name
14.3 Transport hazard class(es)
14.4 Packing group
14.5 Environmental hazards
Not regulated Not regulated Not applicable

14.6 Special Precautions for Users

Special Provisions None

#### **IMDG**

14.1 UN number or ID numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

**14.7 Maritime transport in bulk** No information available

according to IMO instruments

#### RID

14.1UN numberNot regulated14.2UN proper shipping nameNot regulated14.3Transport hazard class(es)Not regulated14.4Packing groupNot regulated14.5Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

#### <u>ADR</u>

14.1 UN number or ID number
14.2 UN proper shipping name
14.3 Transport hazard class(es)
14.4 Packing group
14.5 Environmental hazards
Not regulated
Not regulated
Not regulated
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.

#### Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (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 Significant changes throughout SDS. Review all sections

Revision date 27-Aug-2021

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**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 27-Aug-2021 Previous 23-Nov-2020 Revision Number 2.2

revision date

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

1.1. Product identifier

Product Name Variant II Dual Buffer 2

Catalogue Number(s) 2702502

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 Manufacturer

Bio-Rad Laboratories Inc.

Bio-Rad Laboratories, Diagnostic
4000 Alfred Nobel Drive

Bio-Rad Laboratories, Diagnostic

Hercules, CA 94547 Hercules, California 94547

USA USA

Bio-Rad Laboratories, Diagnostic Group Bio-Rad Laboratories Ltd

The Junction Station Road Watford, WD17 1ET

**Legal Entity / Contact Address** 

UK

For further information, please contact

**Technical Service** 00800 00246 723

Techsupport.UK@bio-rad.com

1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

### **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

Chemical name	Weight-%	REACH registration number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water 7732-18-5	50 - 100	No data available	231-791-2	No data available	-	-	-
Phosphoric acid, monosodium salt, monohydrate 10049-21-5	0.3 - 0.999	No data available	-	No data available	-	-	-
Sodium phosphate dibasic 7558-79-4	0.3 - 0.999	No data available	231-448-7	No data available	-	-	-
1,3-Propanediol, 2-[bis(2-hydroxyethy I)amino]-2-(hydroxy methyl)- 6976-37-0	0.1 - 0.299	No data available	230-237-7	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) STOT SE 3 (H335)	-	-	-
Sodium azide 26628-22-8	0.01 - 0.099	No data available	247-852-1	Acute Tox. 2 (H300) (EUH032) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	-	-	-

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 >=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 physician.

**Skin contact** Wash skin with soap and water. In the case of skin irritation or allergic reactions see a

physician.

**Ingestion** Rinse mouth.

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

**Symptoms** No information available.

### 4.3. Indication of any immediate medical attention and special treatment needed

**Note to physicians** Treat symptomatically.

## **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

Ensure adequate ventilation. Personal precautions

Use personal protection recommended in Section 8. For emergency responders

6.2. Environmental precautions

See Section 12 for additional Ecological Information. **Environmental precautions** 

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** Store according to product and label instructions.

7.3. Specific end use(s)

**Identified uses** 

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.

Chemical name	European Union	Austria	Belgium	Bu	Igaria	Croatia
Sodium azide	TWA: 0.1 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup>	-	STEL: 0.3 mg/m <sup>3</sup>		TWA: 0.1 mg/m <sup>3</sup>
26628-22-8	STEL: 0.3 mg/m <sup>3</sup>	STEL 0.3 mg/m <sup>3</sup>		TWA: (	0.1 mg/m <sup>3</sup>	STEL: 0.3 mg/m <sup>3</sup>
	*	H*			K*	K*
Chemical name	Cyprus	Czech Republic	Denmark	Estonia		Finland
Sodium azide	-	-	TWA: 0.1 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup>		TWA: 0.1 mg/m <sup>3</sup>
26628-22-8			H*		0.3 mg/m <sup>3</sup>	STEL: 0.3 mg/m <sup>3</sup>
					A*	iho*
Chemical name	France	Germany	Germany MAK	Gı	reece	Hungary
Sodium azide	TWA: 0.1 mg/m <sup>3</sup>	TWA: 0.2 mg/m <sup>3</sup>	TWA: 0.2 mg/m <sup>3</sup>		-	TWA: 0.1 mg/m <sup>3</sup>
26628-22-8	STEL: 0.3 mg/m <sup>3</sup>		Ceiling / Peak: 0.4			STEL: 0.3 mg/m <sup>3</sup>
	*		mg/m³			
Chemical name	Ireland	Italy	Italy REL		atvia	Lithuania
Sodium azide	TWA: 0.1 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup>	-		0.1 mg/m <sup>3</sup>	-
26628-22-8	STEL: 0.3 mg/m <sup>3</sup>	STEL: 0.3 mg/m <sup>3</sup>		STEL:	0.3 mg/m <sup>3</sup>	
	Sk*	pelle*			*	
Chemical name	Luxembourg	Malta	Netherlands		orway	Poland
Sodium azide -		-	TWA: 0.1 mg/m <sup>3</sup>		0.1 mg/m <sup>3</sup>	STEL: 0.3 mg/m <sup>3</sup>
26628-22-8			STEL: 0.3 mg/m <sup>3</sup>	STEL:	0.3 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup>
			H*	-		
Chemical name	Portugal	Romania	Slovakia		ovenia	Spain
Sodium azide	TWA: 0.1 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup>		0.1 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup>
26628-22-8	26628-22-8 STEL: 0.3 mg/m <sup>3</sup>		K*	STEL: STEL mg/m <sup>3</sup>		STEL: 0.3 mg/m <sup>3</sup>
	Ceiling: 0.29 mg/m <sup>3</sup>	P*			K*	vía dérmica*
	Ceiling: 0.11 ppm					
Chaminal v v.	P*		Considerate and a second		1.1	to al I/: a state so
Chemical name	5	weden	Switzerland		United Kingdom	
Sodium azide		-	TWA: 0.2 mg/m <sup>3</sup>		TWA: 0.1 mg/m <sup>3</sup>	
26628-22-8			STEL: 0.4 mg/m <sup>3</sup>		STEL: 0.3 mg/m <sup>3</sup>	
1	l l				Sk*	

#### 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)
Predicted No Effect Concentration
(PNEC)

No information available. No information available.

8.2. Exposure controls

Personal protective equipment

**Eye/face protection** No special protective equipment required.

**Skin and body protection**No special protective equipment required.

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

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

No information available. **Environmental exposure controls** 

## SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state Liquid Colour colourless Odour Odourless.

**Odour threshold** No information available

**Property** Values Remarks • Method

Melting point / freezing point 0 °C 100 °C Boiling point / boiling range

Flammability (solid, gas) No data available

Flammability Limit in Air Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Flash point No data available None known **Autoignition temperature** No data available None known **Decomposition temperature** 

None known

No information available

None known

None known

pH (as aqueous solution) No data available Kinematic viscosity No data available

None known **Dynamic viscosity** No data available None known

Miscible in water Water solubility 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

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 regard 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

Stable under normal conditions. Stability

**Explosion data** 

Sensitivity to mechanical impact None. Sensitivity to static discharge

#### 10.3. Possibility of hazardous reactions

**Possibility of hazardous reactions** Avoid contact with metals. This product contains Sodium azide. Sodium azide can react

with Copper, Brass, Lead, and solder in piping systems to form explosive compounds and

toxic gases.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials Metals.

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** 

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
Sodium phosphate dibasic	= 17 g/kg (Rat)	-	-
Sodium azide	= 27 mg/kg (Rat)	= 20 mg/kg (Rabbit)	-
		= 50 mg/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 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.

**Aspiration hazard** No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

11.2.2. Other information

Other adverse effects No information available.

## **SECTION 12: Ecological information**

#### 12.1. Toxicity

# Ecotoxicity

**Unknown aquatic toxicity**Contains 0 % of components with unknown hazards to the aquatic environment.

Chemical name	Algae/aquatic plants	Fish	Toxicity to	Crustacea
			microorganisms	
Sodium azide	-	LC50: =0.7mg/L (96h,	-	-
		Lepomis macrochirus)		
		LC50: =0.8mg/L (96h,		
		Oncorhynchus mykiss)		
		LC50: =5.46mg/L (96h,		
		Pimephales promelas)		

## 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

Chemical name	PBT and vPvB assessment		
Sodium phosphate dibasic	PBT assessment does not apply		

Variant II Dual Buffer 2 Revision date 27-Aug-2021

1,3-Propanediol, 2-[bis(2-hydroxyethyl)amino]-2-(hydroxymethyl)-	The substance is not PBT / vPvB
Sodium azide	PBT assessment does not apply

#### 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

Flush pipes with water frequently if discarding solutions containing Sodium azide into metal piping systems. 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 numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

### **IMDG**

14.1 UN number or ID numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

14.7 Maritime transport in bulk No information available according to IMO instruments

### RID

14.1UN numberNot regulated14.2UN proper shipping nameNot regulated14.3Transport hazard class(es)Not regulated14.4Packing groupNot regulated14.5Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

### ADR

14.1 UN number or ID number
14.2 UN proper shipping name
14.3 Transport hazard class(es)
14.4 Packing group
14.5 Environmental hazards

Not regulated
Not regulated
Not regulated
Not applicable

14.6 Special Precautions for Users

Special Provisions None

Variant II Dual Buffer 2 Revision date 27-Aug-2021

## **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.

#### Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (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

Variant II Dual Buffer 2 Revision date 27-Aug-2021

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 Significant changes throughout SDS. Review all sections

Revision date 27-Aug-2021

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 20-Aug-2021 Previous 23-Nov-2020 Revision Number 1.2

revision date

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

#### 1.1. Product identifier

Product Name Variant II Dual Wash/Diluent

Catalogue Number(s) 2702503

**EC No** 231-791-2

**CAS No** 7732-18-5

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

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

Bio-Rad Laboratories Inc.

Bio-Rad Laboratories, Diagnostic Group

1000 Alfred Nobel Drive

4000 Alfred Nobel Drive

Hercules, CA 94547 Hercules, California 94547

USA USA

**Legal Entity / Contact Address** 

Bio-Rad Laboratories Ltd

The Junction Station Road Watford, WD17 1ET

UK

For further information, please contact

**Technical Service** 00800 00246 723

Techsupport.UK@bio-rad.com

#### 1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

## **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

#### 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 >=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 physician.

**Skin contact**Wash skin with soap and water. In the case of skin irritation or allergic reactions see a

physician.

**Ingestion** Rinse mouth.

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

**Symptoms** No information available.

4.3. Indication of any immediate medical attention and special treatment needed

## **SECTION 5: Firefighting measures**

## 5.1. Extinguishing media

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.

Revision date 20-Aug-2021

### 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.

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

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

Ensure adequate ventilation. Advice on safe handling

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

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)

Identified uses

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

### **SECTION 8: Exposure controls/personal protection**

8.1. Control parameters

This product, as supplied, does not contain any hazardous materials with occupational **Exposure Limits** 

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) **Predicted No Effect Concentration** 

No information available. No information available.

(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** clear liquid 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

Boiling point / boiling range 100 °C

Flammability (solid, gas) 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

Flash pointNo data availableNone knownAutoignition temperatureNo data availableNone known

Decomposition temperature

pH

None known
None known

H None known pH (as aqueous solution) No data available No information available

Kinematic viscosity

No data available

None known

No data available

None known

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
No data available
None known

Bulk density
No data available
Liquid Density
No data available
No data available

Vapour density No data available None known

Particle characteristics

Particle SizeNo information availableParticle Size DistributionNo information available

#### 9.2. Other information

## 9.2.1. Information with regard 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** 

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 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.

**Aspiration hazard** No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

11.2.2. Other information

Other adverse effects No information available.

## **SECTION 12: Ecological information**

12.1. Toxicity

**Ecotoxicity** 

**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

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

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

products

environmentar legislation.

Contaminated packaging

Do not reuse empty containers.

## **SECTION 14: Transport information**

#### IATA

14.1 UN number or ID number
14.2 UN proper shipping name
14.3 Transport hazard class(es)
14.4 Packing group
14.5 Environmental hazards
Not regulated Not regulated Not applicable

14.6 Special Precautions for Users

Special Provisions None

#### **IMDG**

14.1UN number or ID numberNot regulated14.2UN proper shipping nameNot regulated14.3Transport hazard class(es)Not regulated14.4Packing groupNot regulated14.5Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

**14.7** Maritime transport in bulk No information available

according to IMO instruments

#### RID

14.1 UN numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

#### **ADR**

14.1UN number or ID numberNot regulated14.2UN proper shipping nameNot regulated14.3Transport hazard class(es)Not regulated14.4Packing groupNot regulated14.5Environmental hazardsNot 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)

Revision date 20-Aug-2021

#### **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.

#### Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (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

<u>International Inventories</u> 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

Significant changes throughout SDS. Review all sections **Revision Note** 

20-Aug-2021 **Revision date** 

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 27-Aug-2021 Previous 23-Nov-2020 Revision Number 2.2

revision date

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

1.1. Product identifier

Product Name Variant II Dual Analytical Cartridge

Catalogue Number(s) 2702508

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

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

Bio-Rad Laboratories Inc.

Bio-Rad Laboratories, Diagnostic Group

4000 Alfred Nobel Drive

4000 Alfred Nobel Drive

Hercules, CA 94547 Hercules, California 94547

USA USA

Legal Entity / Contact Address

Bio-Rad Laboratories Ltd

The Junction Station Road Watford, WD17 1ET

UK

For further information, please contact

**Technical Service** 00800 00246 723

Techsupport.UK@bio-rad.com

1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

### **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

Chemical name	Weight-%	REACH registration	EC No	Classification	Specific	M-Factor	M-Factor
		number		according to	concentration		(long-term)
				Regulation (EC) No.	limit (SCL)		
				1272/2008 [CLP]			
Methacrylate Resin	50 - 100	No data available	-	No data available	-	-	-
NO-CAS-24							
Water	1 - 2.5	No data available	231-791-2	No data available	-	-	-
7732-18-5							

#### 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 >=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 physician.

**Skin contact**Wash skin with soap and water. In the case of skin irritation or allergic reactions see a

physician.

**Ingestion** Rinse mouth.

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

**Symptoms** No information available.

4.3. Indication of any immediate medical attention and special treatment needed

## **SECTION 5: Firefighting measures**

5.1. Extinguishing media

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.

Revision date 27-Aug-2021

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

Ensure adequate ventilation. Personal precautions

Use personal protection recommended in Section 8. For emergency responders

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** Store according to product and label instructions.

7.3. Specific end use(s)

**Identified uses** 

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

## **SECTION 8: Exposure controls/personal protection**

8.1. Control parameters

This product, as supplied, does not contain any hazardous materials with occupational **Exposure Limits** 

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)
Predicted No Effect Concentration

Predicted No Effect Concentratio (PNEC)

No information available. No information available.

8.2. Exposure controls

Personal protective equipment

**Eve/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.

Revision date 27-Aug-2021

**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 Solid
Appearance solid
Colour white
Odour Slight.

Odour threshold No information available

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

Melting point / freezing pointNo data availableNone knownBoiling point / boiling rangeNo data availableNone knownFlammability (solid, gas)No data availableNone knownFlammability Limit in AirNone known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Flash point No data available None known Autoignition temperature No data available None known Decomposition temperature None known

pH None known

pH (as aqueous solution)

Kinematic viscosity

Dynamic viscosity

No data available

No data available

No data available

None known

No data available

None known

Water solubility Insoluble 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
No data available
None known

Bulk density
No data available
Liquid Density
No data available
No data available

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 regard to physical hazard classes

Revision date 27-Aug-2021

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

Stable under normal conditions. Stability

**Explosion data** 

Sensitivity to mechanical impact None. Sensitivity to static discharge

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.

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

Symptoms related to the physical, chemical and toxicological characteristics

No information available. **Symptoms** 

Acute toxicity

**Numerical measures of toxicity** 

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-

Revision date 27-Aug-2021

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 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.

No information available. **Aspiration hazard** 

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

11.2.2. Other information

Other adverse effects No information available.

## **SECTION 12: Ecological information**

12.1. Toxicity

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

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 numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

### <u>IMDG</u>

14.1 UN number or ID number
 14.2 UN proper shipping name
 14.3 Transport hazard class(es)
 14.4 Packing group
 14.5 Environmental hazards
 Not regulated Not regulated Not applicable

14.6 Special Precautions for Users

Special Provisions No.

**14.7 Maritime transport in bulk** No information available

according to IMO instruments

### <u>RID</u>

14.1 UN numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

ADR

14.1 UN number or ID numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

## **SECTION 15: Regulatory information**

Revision date 27-Aug-2021

#### 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.

#### Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (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

<u>International Inventories</u> 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** Significant changes throughout SDS. Review all sections

Revision date 27-Aug-2021

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 26-Aug-2021 Previous 23-Nov-2020 Revision Number 1.2

revision date

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

1.1. Product identifier

Product Name Variant II Dual B-Thal Calibrator Level 1

Catalogue Number(s) 2702505

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

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

Bio-Rad Laboratories Inc.

Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
4000 Alfred Nobel Drive

1000 Alfred Nobel Drive 4000 Alfred Nobel Drive Hercules, CA 94547 Hercules, California 94547

USA USA

Legal Entity / Contact Address

Bio-Rad Laboratories Ltd

The Junction Station Road Watford, WD17 1ET

UK

For further information, please contact

**Technical Service** 00800 00246 723

Techsupport.UK@bio-rad.com

1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

## **SECTION 2: Hazards identification**

### 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

### 2.2. Label elements

#### **Hazard statements**

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

#### 2.3. Other hazards

## **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Not applicable

#### 3.2 Mixtures

Chemical name	Weight-%	REACH registration number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sucrose 57-50-1	50 - 100	No data available	200-334-9	No data available	-	-	-
Gentamicin, sulfate (salt) 1405-41-0	0.01 - 0.099	No data 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**

No information available

This product does not contain candidate substances of very high concern at a concentration >=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. Rinse

thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a physician.

**Skin contact** Wash with soap and water.

Ingestion Call a physician. Contains human source material and / or potentially infectious

components.

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

**Symptoms** No information available.

4.3. Indication of any immediate medical attention and special treatment needed

## **SECTION 5: Firefighting measures**

5.1. Extinguishing media

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.

Revision date 26-Aug-2021

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** Do not allow into any sewer, on the ground or into any body of water.

Methods for cleaning up Clean contaminated surface thoroughly. Use:. Disinfectant.

**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)

Identified uses

**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	-	-	-	TWA: 10.0 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>
57-50-1					STEL: 20 mg/m <sup>3</sup>
Chemical name	Cyprus	Czech Republic	Denmark	Estonia	Finland
Chemical name Sucrose	Cyprus -	Czech Republic -	Denmark -	Estonia TWA: 10 mg/m <sup>3</sup>	Finland -

France

TWA: 10 mg/m<sup>3</sup>

Ireland

TWA: 10 mg/m<sup>3</sup>

STEL: 20 mg/m<sup>3</sup>

Portugal

TWA: 10 mg/m<sup>3</sup>

Chemical name

Sucrose

57-50-1 Chemical name

> Sucrose 57-50-1

Chemical name

Sucrose 57-50-1 Chemical name

Sucrose

57-50-1

	Revision date 26-Aug-2021						
(	Greece	Hungary					
	-	-					
	Latvia	Lithuania					
	TWA: 5 mg/m <sup>3</sup>	-					
	Slovenia	Spain					
	=	TWA: 10 mg/m <sup>3</sup>					

United Kingdom

TWA: 10 mg/m<sup>3</sup> STEL: 20 mg/m<sup>3</sup>

### Biological occupational exposure limits

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

Germany

Italy

Romania

Derived No Effect Level (DNEL)
Predicted No Effect Concentration
(PNEC)

No information available. No information available.

Sweden

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.

Germany MAK

Italy REL

Slovakia

Switzerland

**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 stateSolidAppearancegranulesColourwhiteOdourOdourless.

Odour threshold No information available

Property Values Remarks • Method

Melting point / freezing pointNo data availableNone knownBoiling point / boiling rangeNo data availableNone knownFlammability (solid, gas)No data availableNone knownFlammability Limit in AirNone known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Flash pointNo data availableNone knownAutoignition temperatureNo data availableNone knownDecomposition temperatureNone known

Revision date 26-Aug-2021

pH None known

pH (as aqueous solution) No data available No information available

Kinematic viscosity
No data available
None known
No data available
None known
No data available

Dynamic viscosity

No data available

No Water solubility

Insoluble in water

Solubility(ies)No data availableNone knownPartition coefficientNo data availableNone knownVapour pressureNo data availableNone knownRelative densityNo data availableNone known

Bulk density
No data available
Liquid Density
No data available

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 regard 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

The following values are calculated based on chapter 3.1 of the GHS document

**ATEmix (oral)** 29,819.30 mg/kg

**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 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.

**Aspiration hazard** No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

11.2.2. Other information

Other adverse effects No information available.

Revision date 26-Aug-2021

## **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

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 numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

**IMDG** 

14.1UN number or ID numberNot regulated14.2UN proper shipping nameNot regulated14.3Transport hazard class(es)Not regulated14.4Packing groupNot regulated14.5Environmental hazardsNot applicable

14.6 Special Precautions for Users

Revision date 26-Aug-2021

\_\_\_\_\_

Special Provisions

None No information available

14.7 Maritime transport in bulk according to IMO instruments

חוכ

14.1 UN numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

ADR

14.1UN number or ID numberNot regulated14.2UN proper shipping nameNot regulated14.3Transport hazard class(es)Not regulated14.4Packing groupNot regulated14.5Environmental hazardsNot 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.

#### Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (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

<u>International Inventories</u> 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) 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 Significant changes throughout SDS. Review all sections

Revision date 26-Aug-2021

Revision date 26-Aug-2021

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 Previous** 30-Oct-2020 **Revision Number 1** 26-Aug-2021

revision date

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

1.1. Product identifier

**Product Name** Variant II Dual B-Thal Calibrator Level 2

2702506 Catalogue Number(s)

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** Manufacturer

Bio-Rad Laboratories Inc. Bio-Rad Laboratories, Diagnostic Group 1000 Alfred Nobel Drive 4000 Alfred Nobel Drive

Hercules, CA 94547 Hercules, California 94547 USA

**USA** 

**Legal Entity / Contact Address** 

Bio-Rad Laboratories Ltd

The Junction Station Road Watford, WD17 1ET

UK

For further information, please contact

**Technical Service** 00800 00246 723

Techsupport.UK@bio-rad.com

1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

## **SECTION 2: Hazards identification**

### 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

### 2.2. Label elements

#### **Hazard statements**

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

#### 2.3. Other hazards

## **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Not applicable

#### 3.2 Mixtures

Chemical name	Weight-%	REACH registration number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sucrose 57-50-1	50 - 100	No data available	200-334-9	No data available	-	-	-
Gentamicin, sulfate (salt) 1405-41-0	0.01 - 0.099	No data 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**

No information available

This product does not contain candidate substances of very high concern at a concentration >=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. Rinse

thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a physician.

**Skin contact** Wash with soap and water.

Ingestion Call a physician. Contains human source material and / or potentially infectious

components.

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

**Symptoms** No information available.

4.3. Indication of any immediate medical attention and special treatment needed

## **SECTION 5: Firefighting measures**

5.1. Extinguishing media

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.

Revision date 26-Aug-2021

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** Do not allow into any sewer, on the ground or into any body of water.

Methods for cleaning up Clean contaminated surface thoroughly. Use:. Disinfectant.

**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)

Identified uses

**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	-	-	-	TWA: 10.0 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>
57-50-1					STEL: 20 mg/m <sup>3</sup>
Chemical name	Cyprus	Czech Republic	Denmark	Estonia	Finland
Chemical name Sucrose	Cyprus -	Czech Republic -	Denmark -	Estonia TWA: 10 mg/m <sup>3</sup>	Finland -

France

TWA: 10 mg/m<sup>3</sup>

Ireland

TWA: 10 mg/m<sup>3</sup>

STEL: 20 mg/m<sup>3</sup>

Portugal

TWA: 10 mg/m<sup>3</sup>

Chemical name

Sucrose

57-50-1 Chemical name

> Sucrose 57-50-1

Chemical name

Sucrose 57-50-1 Chemical name

Sucrose

57-50-1

	Revision o	date 26-Aug-2021
K	Greece	Hungary
	-	-
	Latvia	Lithuania
	TWA: 5 mg/m <sup>3</sup>	-
	Slovenia	Spain
	-	TWA: 10 mg/m <sup>3</sup>

United Kingdom

TWA: 10 mg/m<sup>3</sup>

STEL: 20 mg/m<sup>3</sup>

### **Biological occupational exposure limits**

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

Germany

Italy

Romania

Germany MAI

Italy REL

Slovakia

Switzerland

**Derived No Effect Level (DNEL) Predicted No Effect Concentration** (PNEC)

No information available. No information available.

Sweden

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.

No information available. **Environmental exposure controls** 

## SECTION 9: Physical and chemical properties

## 9.1. Information on basic physical and chemical properties

Physical state Solid **Appearance** granules Colour white Odour Odourless.

**Odour threshold** No information available

Property Values Remarks • Method

Melting point / freezing point No data available None known No data available None known Boiling point / boiling range 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

Flash point No data available None known **Autoignition temperature** No data available None known **Decomposition temperature** None known

No data available

Revision date 26-Aug-2021

pH None known

pH (as aqueous solution) No data available No information available

Kinematic viscosity
No data available
None known
No data available
None known
No data available

Water solubility Insoluble in water

Solubility(ies)No data availableNone knownPartition coefficientNo data availableNone knownVapour pressureNo data availableNone knownRelative densityNo data availableNone known

Bulk density
No data available
Liquid Density
No data available

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 regard 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

The following values are calculated based on chapter 3.1 of the GHS document

**ATEmix (oral)** 29,819.30 mg/kg

**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 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.

**Aspiration hazard** No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

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

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

14.1UN number or ID numberNot regulated14.2UN proper shipping nameNot regulated14.3Transport hazard class(es)Not regulated14.4Packing groupNot regulated14.5Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

**IMDG** 

14.1UN number or ID numberNot regulated14.2UN proper shipping nameNot regulated14.3Transport hazard class(es)Not regulated14.4Packing groupNot regulated14.5Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

14.7 Maritime transport in bulk No information available according to IMO instruments

RID

14.1 UN numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

ADR

14.1 UN number or ID number
14.2 UN proper shipping name
14.3 Transport hazard class(es)
14.4 Packing group
14.5 Environmental hazards
Not regulated
Not regulated
Not regulated
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.

### Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (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

<u>International Inventories</u> 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) 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 Significant changes throughout SDS. Review all sections

Revision date 26-Aug-2021

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**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 26-Aug-2021 Previous 30-Oct-2020 Revision Number 1

revision date

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

1.1. Product identifier

Product Name Variant II Dual HbA1c Calibrator Level 1

Catalogue Number(s) 2702512

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 Manufacturer

Bio-Rad Laboratories Inc.

Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
4000 Alfred Nobel Drive

Hercules, CA 94547 Hercules, California 94547

USA USA

Legal Entity / Contact Address

Bio-Rad Laboratories Ltd

The Junction Station Road Watford, WD17 1ET

UK

For further information, please contact

**Technical Service** 00800 00246 723

Techsupport.UK@bio-rad.com

1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

# **SECTION 2: Hazards identification**

### 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

### 2.2. Label elements

#### **Hazard statements**

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

#### 2.3. Other hazards

# **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Not applicable

#### 3.2 Mixtures

Chemical name	Weight-%	REACH registration number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sucrose 57-50-1	50 - 100	No data available	200-334-9	No data available	-	-	-
Gentamicin, sulfate (salt) 1405-41-0	0.01 - 0.099	No data 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**

No information available

This product does not contain candidate substances of very high concern at a concentration >=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. Rinse

thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a physician.

**Skin contact** Wash with soap and water.

Ingestion Call a physician. Contains human source material and / or potentially infectious

components.

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

**Symptoms** No information available.

4.3. Indication of any immediate medical attention and special treatment needed

# **SECTION 5: Firefighting measures**

5.1. Extinguishing media

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** Do not allow into any sewer, on the ground or into any body of water.

Methods for cleaning up Clean contaminated surface thoroughly. Use:. Disinfectant.

**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)

**Identified uses** 

**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	-	-	-	TWA: 10.0 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>
57-50-1					STEL: 20 mg/m <sup>3</sup>
Chemical name	Cyprus	Czech Republic	Denmark	Estonia	Finland
Chemical name Sucrose	Cyprus -	Czech Republic -	Denmark -	Estonia TWA: 10 mg/m <sup>3</sup>	Finland -

Chemical name		France	Germany	Germany MAK	G	eece	Hungary
Sucrose 57-50-1	TWA: 10 mg/m <sup>3</sup>		•	-		-	-
Chemical name		Ireland	Italy	Italy REL	La	atvia	Lithuania
Sucrose 57-50-1		A: 10 mg/m <sup>3</sup> L: 20 mg/m <sup>3</sup>	-	-	TWA:	5 mg/m <sup>3</sup>	-
Chemical name		Portugal	Romania	Slovakia	Slo	venia	Spain
Sucrose 57-50-1	TW	A: 10 mg/m <sup>3</sup>	-	-		-	TWA: 10 mg/m <sup>3</sup>
Chemical name		Sı	weden	Switzerland		Uni	ted Kingdom
Sucrose 57-50-1			-	-			/A: 10 mg/m³ EL: 20 mg/m³

### **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) Predicted No Effect Concentration** (PNEC)

No information available. 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.

No information available. **Environmental exposure controls** 

# SECTION 9: Physical and chemical properties

# 9.1. Information on basic physical and chemical properties

Physical state Solid **Appearance** granules Colour white Odour Odourless.

**Odour threshold** No information available

Property Values Remarks • Method

Melting point / freezing point No data available None known None known No data available **Boiling point / boiling range** Flammability (solid, gas) No data available None known Flammability Limit in Air None known

Upper flammability or explosive

No data available limits

No data available Lower flammability or explosive

limits

Flash point No data available None known **Autoignition temperature** No data available None known **Decomposition temperature** None known

pН 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 Insoluble in water

Solubility(ies) No data available None known No data available None known Partition coefficient No data available Vapour pressure None known Relative density No data available None known

No data available **Bulk density Liquid Density** No data available

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 regard to physical hazard classes

Not applicable

9.2.2. Other safety characteristics

No information available

# SECTION 10: Stability and reactivity

10.1. Reactivity

No information available. Reactivity

10.2. Chemical stability

Stability Stable under normal conditions.

**Explosion data** 

Sensitivity to mechanical impact None. Sensitivity to static discharge

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

None known based on information supplied. Conditions to avoid

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

The following values are calculated based on chapter 3.1 of the GHS document

**ATEmix (oral)** 29,819.30 mg/kg

**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 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.

**Aspiration hazard** No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

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

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 numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

**IMDG** 

14.1UN number or ID numberNot regulated14.2UN proper shipping nameNot regulated14.3Transport hazard class(es)Not regulated14.4Packing groupNot regulated14.5Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

14.7 Maritime transport in bulk No information available according to IMO instruments

RID

14.1 UN numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

ADR

14.1UN number or ID numberNot regulated14.2UN proper shipping nameNot regulated14.3Transport hazard class(es)Not regulated14.4Packing groupNot regulated14.5Environmental hazardsNot 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.

### Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (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

<u>International Inventories</u> 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) 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 Significant changes throughout SDS. Review all sections

Revision date 26-Aug-2021

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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

**Legal Entity / Contact Address** 

Bio-Rad Laboratories Ltd

Watford, WD17 1ET

The Junction

Station Road

UK

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

Revision date 26-Aug-2021 Previous 30-Oct-2020 Revision Number 1

revision date

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

1.1. Product identifier

Product Name Variant II Dual HbA1c Calibrator Level 2

Catalogue Number(s) 2702513

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

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

Bio-Rad Laboratories Inc.

Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
4000 Alfred Nobel Drive

Hercules, CA 94547 Hercules, California 94547

USA USA

For further information, please contact

**Technical Service** 00800 00246 723

Techsupport.UK@bio-rad.com

1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

# **SECTION 2: Hazards identification**

### 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

### 2.2. Label elements

#### **Hazard statements**

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

#### 2.3. Other hazards

# **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

EGHS / BE Page 88/97

Not applicable

#### 3.2 Mixtures

Chemical name	Weight-%	REACH registration number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sucrose 57-50-1	50 - 100	No data available	200-334-9	No data available	-	-	-
Gentamicin, sulfate (salt) 1405-41-0	0.01 - 0.099	No data 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**

No information available

This product does not contain candidate substances of very high concern at a concentration >=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. Rinse

thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a physician.

**Skin contact** Wash with soap and water.

Ingestion Call a physician. Contains human source material and / or potentially infectious

components.

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

**Symptoms** No information available.

4.3. Indication of any immediate medical attention and special treatment needed

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

# **SECTION 5: Firefighting measures**

5.1. Extinguishing media

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 No information available.

chemical

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** Do not allow into any sewer, on the ground or into any body of water.

Methods for cleaning up Clean contaminated surface thoroughly. Use:. Disinfectant.

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)

Identified uses

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	-	-	-	TWA: 10.0 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>
57-50-1					STEL: 20 mg/m <sup>3</sup>
Chemical name	Cyprus	Czech Republic	Denmark	Estonia	Finland

Sucrose 57-50-1	-	-	-	TWA:	10 mg/m <sup>3</sup>	-
Chemical name	France	Germany	Germany MAK	Gr	eece	Hungary
Sucrose 57-50-1	TWA: 10 mg/m <sup>3</sup>	-	-		-	-
Chemical name	Ireland	Italy	Italy REL	La	atvia	Lithuania
Sucrose 57-50-1	TWA: 10 mg/m <sup>3</sup> STEL: 20 mg/m <sup>3</sup>	-	-	TWA:	5 mg/m <sup>3</sup>	-
Chemical name	Portugal	Romania	Slovakia	Slo	venia	Spain
Sucrose 57-50-1	TWA: 10 mg/m <sup>3</sup>	-	-		-	TWA: 10 mg/m <sup>3</sup>
Chemical name	S	weden	Switzerland		United Kingdom	
Sucrose 57-50-1				/A: 10 mg/m³ EL: 20 mg/m³		

## **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)
Predicted No Effect Concentration
(PNEC)

No information available. 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 stateSolidAppearancegranulesColourwhiteOdourOdourless.

Odour threshold No information available

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

Melting point / freezing pointNo data availableNone knownBoiling point / boiling rangeNo data availableNone knownFlammability (solid, gas)No data availableNone knownFlammability Limit in AirNone known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Flash point No data available None known

No data available **Autoignition temperature** None known **Decomposition temperature** None known

None known pН 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 Insoluble in water

Solubility(ies) No data available None known None known **Partition coefficient** No data available No data available None known Vapour pressure Relative density No data available None known

**Bulk density** No data available **Liquid Density** No data available

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 regard to physical hazard classes

Not applicable

#### 9.2.2. Other safety characteristics

No information available

# **SECTION 10: Stability and reactivity**

10.1. Reactivity

No information available. Reactivity

10.2. Chemical stability

Stability Stable under normal conditions.

**Explosion data** 

Sensitivity to mechanical impact None. Sensitivity to static discharge

10.3. Possibility of hazardous reactions

**Possibility of hazardous reactions** None under normal processing.

10.4. Conditions to avoid

None known based on information supplied. Conditions to avoid

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.

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

Symptoms related to the physical, chemical and toxicological characteristics

No information available. **Symptoms** 

Acute toxicity

**Numerical measures of toxicity** 

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral) 29,819.30 mg/kg

**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

No information available. Skin corrosion/irritation

No information available. Serious eye damage/eye irritation

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

No information available. Carcinogenicity

No information available. Reproductive toxicity

No information available. STOT - single exposure

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** No information available.

### 11.2.2. Other information

No information available. Other adverse effects

# **SECTION 12: Ecological information**

12.1. Toxicity

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

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.

12.2. Persistence and degradability

No information available. Persistence and degradability

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

12.6. Endocrine disrupting properties

No information available. **Endocrine disrupting properties** 

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 14.5 Environmental hazards**Not regulated
Not applicable

14.6 Special Precautions for Users

Special Provisions Non

14.7 Maritime transport in bulk No information available according to IMO instruments

<u>RID</u>

14.1 UN numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

<u>ADR</u>

14.1UN number or ID numberNot regulated14.2UN proper shipping nameNot regulated14.3Transport hazard class(es)Not regulated14.4Packing groupNot regulated14.5Environmental hazardsNot 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.

### Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (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

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### **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) 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

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European Chemicals Agency (ECHA) (ECHA API)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGL(s))

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U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

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

World Health Organization

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**Revision date** 

26-Aug-2021

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**End of Safety Data Sheet**