



# 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-Apr-2022

Previous revision date 26-Apr-2022

Revision Number 1

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

### 1.1. Product identifier

**Product Name** Biotestcell A2  
**Catalogue Number(s)** 12012454  
**Safety data sheet number** 186127  
**Pure substance/mixture** Mixture

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

**Recommended use** In vitro diagnostic  
**Uses advised against** No information available

### 1.3. Details of the supplier of the safety data sheet

#### **Corporate Headquarters**

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

#### **Manufacturer**

Bio-Rad Medical Diagnostics GmbH  
Industriestr. 1  
63303 Dreieich  
Germany  
e-mail: contact.bmd@bio-rad.com

#### **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

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**

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

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

**SECTION 4: First aid measures****4.1. Description of first aid measures**

Inhalation	Remove to fresh air.
Eye contact	Contains human source material and / or potentially infectious components. Call a physician. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Skin contact	Wash with soap and water.
Ingestion	Contains human source material and / or potentially infectious components. Call a physician.

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

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

Note to physicians	Contains human source material and / or potentially infectious components.
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**SECTION 5: Firefighting measures****5.1. Extinguishing media**

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
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.
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**5.3. Advice for firefighters**

**Special protective equipment and precautions for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

**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** Use: Disinfectant. Clean contaminated surface thoroughly.

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

**6.4. Reference to other sections**

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

**SECTION 7: Handling and storage****7.1. Precautions for safe handling**

**Advice on safe handling** Ensure adequate ventilation.

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

**7.2. Conditions for safe storage, including any incompatibilities**

**Storage Conditions** Store according to product and label instructions.

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

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

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters****Exposure Limits****Biological occupational exposure limits**

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

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

## 8.2. Exposure controls

### Personal protective equipment

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

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	Liquid
Colour	red
Odour	No information available.
Odour threshold	No information available

Property	Values	Remarks • Method
Melting point / freezing point	No data available	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 limits	No data available	
Lower flammability or explosive limits	No data available	
Flash point	No data available	None known
Autoignition temperature	1010 °C	
Decomposition temperature		None known
pH		None known
pH (as aqueous solution)	No data available	No information available
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	Miscible in water	
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Vapour pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
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  
Component Information

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

<b>Skin corrosion/irritation</b>	No information available.
<b>Serious eye damage/eye irritation</b>	No information available.
<b>Respiratory or skin sensitization</b>	No information available.
<b>Germ cell mutagenicity</b>	No information available.
<b>Carcinogenicity</b>	No information available.
<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<b>Aspiration hazard</b>	No information available.

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

<b>Endocrine disrupting properties</b>	No information available.
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**11.2.2. Other information**

<b>Other adverse effects</b>	No information available.
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**SECTION 12: Ecological information****12.1. Toxicity****Ecotoxicity**

<b>Unknown aquatic toxicity</b>	Contains 0 % of components with unknown hazards to the aquatic environment.
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**12.2. Persistence and degradability**

<b>Persistence and degradability</b>	No information available.
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**12.3. Bioaccumulative potential**

<b>Bioaccumulation</b>	There is no data for this product.
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**12.4. Mobility in soil**

<b>Mobility in soil</b>	No information available.
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**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 number** Not regulated

**14.2 UN proper shipping name** Not regulated

**14.3 Transport hazard class(es)** Not regulated

**14.4 Packing group** Not regulated

**14.5 Environmental hazards** Not applicable

**14.6 Special Precautions for Users**

**Special Provisions** None

**IMDG**

**14.1 UN number or ID number** Not regulated

**14.2 UN proper shipping name** Not regulated

**14.3 Transport hazard class(es)** Not regulated

**14.4 Packing group** Not regulated

**14.5 Environmental hazards** Not applicable

**14.6 Special Precautions for Users**

**Special Provisions** None

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

**RID**

**14.1 UN number** Not regulated

**14.2 UN proper shipping name** Not regulated

**14.3 Transport hazard class(es)** Not regulated

**14.4 Packing group** Not regulated

**14.5 Environmental hazards** Not applicable

**14.6 Special Precautions for Users**

**Special Provisions** None

**ADR**

**14.1 UN number or ID number** Not regulated

**14.2 UN proper shipping name** Not regulated

**14.3 Transport hazard class(es)** Not regulated

**14.4 Packing group** Not regulated

**14.5 Environmental hazards** Not applicable

**14.6 Special Precautions for Users**

**Special Provisions** None

## SECTION 15: Regulatory information

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

#### National regulations

##### France

Occupational Illnesses (R-463-3, France)

##### Germany

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

##### Netherlands

##### 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

#### **Plant protection products directive (91/414/EEC)**

#### **EU - Biocides**

#### 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)  
 Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)  
 NIOSH (National Institute for Occupational Safety and Health)  
 National Library of Medicine's ChemID Plus (NLM CIP)  
 National Library of Medicine's PubMed database (NLM PUBMED)  
 National Toxicology Program (NTP)  
 New Zealand's Chemical Classification and Information Database (CCID)  
 Organization for Economic Co-operation and Development Environment, Health, and Safety Publications  
 Organization for Economic Co-operation and Development High Production Volume Chemicals Program  
 Organization for Economic Co-operation and Development Screening Information Data Set  
 World Health Organization

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

**Revision date** 26-Apr-2022

**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**