



# 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 15-Sep-2023

Revision Number 1.2

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

### 1.1. Product identifier

**Product Name** Exact Diagnostics BKV Urine LOD  
**Catalogue Number(s)** BKVULOD  
**Nanoforms** Not applicable  
**Pure substance/mixture** Mixture

Contains Guanidine, hydrochloride (1:1)

### 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**

Exact Diagnostics  
100 South Jones Street, Suite 100,  
Fort Worth, Texas 76104  
USA

#### **Legal Entity / Contact Address**

Bio-Rad Laboratories Ltd  
The Junction  
Station Road  
Watford, WD17 1ET  
UK

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

Bio-Rad Laboratories (Pty) Ltd.  
34 Bolton Road  
Parkwood, Johannesburg 2193  
South Africa

For further information, please contact

**Technical Service** 00800 00246 723  
Ireland: Techsupport.UK@bio-rad.com  
India: support.india@bio-rad.com  
South Africa: cdg\_techsupport\_eemea@bio-rad.com

### 1.4. Emergency telephone number

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

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute toxicity - Oral	Category 4 - (H302)
Skin corrosion/irritation	Category 2 - (H315)
Serious eye damage/eye irritation	Category 2 - (H319)

**2.2. Label elements**

Contains Guanidine, hydrochloride (1:1)

**Signal word**

Warning

**Hazard statements**

H302 - Harmful if swallowed

H315 - Causes skin irritation

H319 - Causes serious eye irritation

**Precautionary Statements - EU (§28, 1272/2008)**

P264 - Wash face, hands and any exposed skin thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P337 + P313 - If eye irritation persists: Get medical advice/attention

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

P280 - Wear protective gloves/protective clothing/eye protection/face protection

**2.3. Other hazards**

Contains components derived from human urine.

Contains human source material and / or potentially infectious components

**SECTION 3: Composition/information on ingredients****3.1 Substances**

Not applicable

**3.2 Mixtures**

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Guanidine, hydrochloride (1:1) 50-01-1	20 - 35	No data available	(607-148-00-0) 200-002-3	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)	-	-	-

**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

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
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Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Guanidine, hydrochloride (1:1) 50-01-1	475	2000	Inhalation LC50 Rat 3.181 mg/L 4 h (females, aerosol, Source: ECHA_API); Inhalation LC50 Rat 7.655 mg/L 4 h (males, aerosol, Source: ECHA_API)	3.181 7.655	Inhalation LC50 Rat 3.181 mg/L 4 h (females, aerosol, Source: ECHA_API); Inhalation LC50 Rat 7.655 mg/L 4 h (males, aerosol, Source: ECHA_API)

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

<b>General advice</b>	Show this safety data sheet to the doctor in attendance. Contains components derived from human urine.
<b>Inhalation</b>	Remove to fresh air. Get medical attention immediately if symptoms occur.
<b>Eye contact</b>	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists. Contains human source material and / or potentially infectious components. Call a doctor.
<b>Skin contact</b>	Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists. Wash with soap and water.
<b>Ingestion</b>	Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Call a doctor. Contains human source material and / or potentially infectious components.
<b>Self-protection of the first aider</b>	Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

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

<b>Symptoms</b>	May cause redness and tearing of the eyes. Burning sensation.
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### 4.3. Indication of any immediate medical attention and special treatment needed

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

### 5.1. Extinguishing media

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Large Fire</b>	CAUTION: Use of water spray when fighting fire may be inefficient.
<b>Unsuitable extinguishing media</b>	Do not scatter spilled material with high pressure water streams.

### 5.2. Special hazards arising from the substance or mixture

<b>Specific hazards arising from the</b>	No information available.
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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** Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required.

**Other information** Refer to protective measures listed in Sections 7 and 8.

**For emergency responders** Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

**Environmental precautions** Prevent further leakage or spillage if safe to do so.

### 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** Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash it before reuse.

**General hygiene considerations** Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Avoid contact with skin, eyes or clothing. Follow universal and standard precautions for handling potentially infectious materials.

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

**Storage Conditions** Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. 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

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

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

<b>Derived No Effect Level (DNEL)</b>	No information available.
<b>Predicted No Effect Concentration (PNEC)</b>	No information available.

**8.2. Exposure controls****Personal protective equipment**

<b>Eye/face protection</b>	Wear safety glasses with side shields (or goggles).
<b>Hand protection</b>	Wear suitable gloves. Impervious gloves.
<b>Skin and body protection</b>	Wear suitable protective clothing.
<b>Respiratory protection</b>	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
<b>General hygiene considerations</b>	Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Avoid contact with skin, eyes or clothing. Follow universal and standard precautions for handling potentially infectious materials.
<b>Environmental exposure controls</b>	No information available.

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

<b>Physical state</b>	Liquid
<b>Appearance</b>	Clear
<b>Colour</b>	light yellow
<b>Odour</b>	No information available.
<b>Odour threshold</b>	No information available

<b>Property</b>	<b>Values</b>	<b>Remarks • Method</b>
<b>Melting point / freezing point</b>	No data available	None known
<b>Boiling point / boiling range</b>	No data available	None known
<b>Flammability (solid, gas)</b>	No data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Flash point</b>	No data available	None known
<b>Autoignition temperature</b>	No data available	None known
<b>Decomposition temperature</b>		None known
<b>pH</b>	7.4-7.6	
<b>pH (as aqueous solution)</b>	No data available	No information available
<b>Kinematic viscosity</b>	No data available	None known
<b>Dynamic viscosity</b>	No data available	None known
<b>Water solubility</b>	Miscible in water	
<b>Solubility(ies)</b>	No data available	None known
<b>Partition coefficient</b>	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 regards to physical hazard classes

Not applicable

### 9.2.2. Other safety characteristics

No information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Reactivity No information available.

### 10.2. Chemical stability

Stability Stable under normal conditions.

#### Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

### 10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

### 10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

### 10.5. Incompatible materials

Incompatible materials Strong acids. Strong bases. Strong oxidising agents.

### 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. May cause irritation of respiratory tract.
Eye contact	Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.
Skin contact	Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components).

**Ingestion**

Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea. Harmful if swallowed. (based on components).

**Symptoms related to the physical, chemical and toxicological characteristics****Symptoms**

Redness. May cause redness and tearing of the eyes.

**Acute toxicity****Numerical measures of toxicity**

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

ATEmix (oral) 1,816.10 mg/kg

Unknown acute toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Guanidine, hydrochloride (1:1)	= 475 mg/kg ( Rat )	> 2000 mg/kg ( Rabbit )	= 3.181 mg/L ( Rat ) 4 h = 7.655 mg/L ( Rat ) 4 h

**Delayed and immediate effects as well as chronic effects from short and long-term exposure****Skin corrosion/irritation**

Classification based on data available for ingredients. Causes skin irritation. May cause skin irritation.

**Serious eye damage/eye irritation**

Classification based on data available for ingredients. Causes serious eye irritation.

**Respiratory or skin sensitisation**

No information available.

**Germ cell mutagenicity**

No information available.

**Carcinogenicity**

No information available.

**Reproductive toxicity**

No information available.

**STOT - single exposure**

No information available.

**STOT - repeated exposure**

No information available.

**Aspiration hazard**

No information available.

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

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

**11.2.2. Other information****Other adverse effects**

No information available.

## SECTION 12: Ecological information

### 12.1. Toxicity

<b>Ecotoxicity</b>	The environmental impact of this product has not been fully investigated.
<b>Unknown aquatic toxicity</b>	Contains 0 % of components with unknown hazards to the aquatic environment.

### 12.2. Persistence and degradability

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

#### Bioaccumulation

#### Component Information

Chemical name	Partition coefficient
Guanidine, hydrochloride (1:1)	-1.7

### 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

Chemical name	PBT and vPvB assessment
Guanidine, hydrochloride (1:1)	The substance is not PBT / vPvB

### 12.6. Endocrine disrupting properties

<b>Endocrine disrupting properties</b>	No information available.
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### 12.7. Other adverse effects

No information available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

<b>Waste from residues/unused products</b>	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
<b>Contaminated packaging</b>	Do not reuse empty containers.

## SECTION 14: Transport information

#### IATA

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



**IMDG**

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

**RID**

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

**ADR**

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

## SECTION 15: Regulatory information

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

#### National regulations

##### Germany

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

##### European Union

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

#### **Authorisations and/or restrictions on use:**

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorisation per REACH Annex XIV
Guanidine, hydrochloride (1:1) - 50-01-1	75.	-

#### **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****Full text of H-Statements referred to under section 3**

H302 - Harmful if swallowed

H315 - Causes skin irritation

H319 - Causes serious eye irritation

**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

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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) (AELG(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)

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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** New Safety Data Sheet

**Revision date** 15-Sep-2023

**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**