



SAFETY DATA SHEET

According to WHS Regulations

Revision date 15-Sep-2023

Revision Number 1.1

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

Product identifier

Product Name Exact Diagnostics BKV Urine LOD

Catalogue Number(s) BKVULOD

Other means of identification

Pure substance/mixture Mixture

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic

Uses advised against No information available

Details of manufacturer or importer

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 Pty Ltd
u1A, 62 Ferndell Street,
South Granville NSW 2142
Australia

For further information, please contact

Technical Service +61 2 9914 2800 or 1800 224 354
sales.australia@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Australia: 61-290372994

Emergency telephone number No information available

SECTION 2: Hazards identification

GHS Classification

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

Label elements

Exclamation mark

**Signal word**

Warning

Hazard statements

H302 - Harmful if swallowed

H315 - Causes skin irritation

H319 - Causes serious eye irritation

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

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

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

If eye irritation persists: Get medical advice/attention

IF ON SKIN: Wash with plenty of water and soap

If skin irritation occurs: Get medical advice/attention

Take off all contaminated clothing and wash it before reuse

IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell

Rinse mouth

Precautionary Statements - Disposal

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

Other hazards which do not result in classification

Contains components derived from human urine

General Hazards

Contains human source material and / or potentially infectious components

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

Not applicable

Mixture

Chemical name	CAS No	Weight-%
Guanidine, hydrochloride (1:1)	50-01-1	20 - 35
Non-hazardous ingredients	Proprietary	Balance

SECTION 4: First aid measures**Description of first aid measures****General advice**

Show this safety data sheet to the doctor in attendance. Contains components derived from human urine.

Emergency telephone number

Poisons Information Centre, Australia: 13 11 26

Poisons Information Centre, New Zealand: 0800 764 766

Inhalation

Remove to fresh air. Get medical attention immediately if symptoms occur.

Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists. Do not rub affected area. 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 doctor.
Skin contact	Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists. Wash skin with soap and water.
Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a doctor. Contains human source material and / or potentially infectious components.
Self-protection of the first aider	Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Symptoms May cause redness and tearing of the eyes. Burning sensation.

Indication of any immediate medical attention and special treatment needed

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

SECTION 5: Firefighting measures**Suitable Extinguishing Media**

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media No information available.

Specific hazards arising from the chemical

Specific hazards arising from the chemical None known.

Special protective actions for fire-fighters

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

SECTION 6: Accidental release measures**Personal precautions, protective equipment and emergency procedures**

Personal precautions 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.

Environmental precautions

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

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.

Precautions to prevent secondary hazards

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

SECTION 7: Handling and storage

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.

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.

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

SECTION 8: Exposure controls/personal protection

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

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

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

Skin and body protection Wear suitable protective clothing.

Hand protection Wear suitable gloves. Impervious gloves.

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

Environmental exposure controls No information available.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Clear
Colour	light yellow
Odour	No information available.
Odour threshold	No information available

Property	Values	Remarks • Method
pH	7.4-7.6	
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapour pressure	No data available	None known
Vapour density	No data available	None known
Relative density	No data available	None known
Water solubility	Miscible in water	
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive properties	Not applicable	
Oxidising properties	Not applicable	
Other information		
Molecular weight	Not applicable	
VOC content	Not applicable	

SECTION 10: Stability and reactivity

Reactivity

Reactivity	No information available.
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Chemical stability

Stability	Stable under normal conditions.
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Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

Possibility of hazardous reactions

Possibility of hazardous reactions	None under normal processing.
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Conditions to avoid

Conditions to avoid None known based on information supplied.

Incompatible materials

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

Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

Acute toxicity

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. Irritating to eyes. (based on components). Causes serious eye irritation.
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 Redness. May cause redness and tearing of the eyes.

Numerical measures of toxicity - Product Information

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

ATEmix (oral) 1,816.10 mg/kg

Unknown acute toxicity

0 % of the mixture consists of ingredient(s) of unknown acute oral 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

See section 16 for terms and abbreviations

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. Irritating to skin.
Serious eye damage/eye irritation	Classification based on data available for ingredients. Causes serious eye irritation.
Respiratory or skin sensitisation	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.

STOT - single exposure Based on available data, the classification criteria are not met.

STOT - repeated exposure Based on available data, the classification criteria are not met.

Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

Ecotoxicity

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

Unknown aquatic toxicity 0 % of the mixture consists of component(s) of unknown hazards to the aquatic environment.

Persistence and degradability

Persistence and degradability No information available.

Bioaccumulative potential

Bioaccumulation There is no data for this product.

Component Information

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

Mobility

Mobility in soil No information available.

Mobility No information available.

Other adverse effects

Other adverse effects No information available.

SECTION 13: Disposal considerations

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

ADG Not regulated

IATA Not regulated

IMDG Not regulated

Transport in bulk according to Annex II of MARPOL and the IBC Code
No information available

SECTION 15: Regulatory information

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

National regulations

Australia

See section 8 for national exposure control parameters

Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)

No poisons schedule number allocated

International Inventories

Contact supplier for inventory compliance status

International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

SECTION 16: Other information

Prepared By Bio-Rad Laboratories, Environmental Health and Safety

Revision date 15-Sep-2023

Revision Note New Safety Data Sheet.

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (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)
Japan GHS Classification
Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications
Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme
Organisation for Economic Co-operation and Development Screening Information Data Set
RTECS (Registry of Toxic Effects of Chemical Substances)
World Health Organization

Disclaimer

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End of Safety Data Sheet