

SAFETY DATA SHEET



Revision date 15-Sep-2023

Revision Number 1.1

1. Identification

Product identifier

Product Name Exact Diagnostics BKV Urine LOD

Other means of identification

Catalog Number(s) BKVULOD

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic

Details of the supplier of the safety data sheet

Corporate Headquarters

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

Manufacturer Address

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

Legal Entity / Contact Address

Bio-Rad Laboratories Inc.
9500 Jeronimo Road
Irvine, California 92618
USA

Technical Service 1(800) 854-6737
qsd.techservice@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC USA: 1 (800) 424-9300

2. Hazard(s) identification

Classification

Acute toxicity - Oral	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Warning

Hazard statements

Harmful if swallowed
Causes skin irritation
Causes serious eye irritation



Appearance Clear	Physical state Liquid	Odor No information available
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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/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 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

Unknown acute toxicity**Other information**

Contains components derived from human urine.

Contains human source material and / or potentially infectious components

3. Composition/information on ingredients**Substance**

Not applicable.

Mixture

Chemical name	CAS No	Weight-%	Trade secret
Guanidine, hydrochloride (1:1)	50-01-1	20 - 35	*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

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.
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. 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 physician.
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 with soap and water.
Ingestion	Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Call a physician. 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 physicians Contains human source material and / or potentially infectious components.

5. Fire-fighting measures

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

Specific hazards arising from the chemical No information available.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

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

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.

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.

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 before reuse.

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.

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.

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).

Hand protection Wear suitable gloves. Impervious 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 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.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Liquid
Appearance Clear
Color light yellow
Odor No information available
Odor threshold No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
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	
Vapor pressure	No data available	None known
Vapor 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	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known

Other information

Explosive properties	No information available
Oxidizing properties	No information available
Softening point	No information available
Molecular weight	No information available
VOC content	No information available
Liquid Density	No information available
Bulk density	No information available

10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	Strong acids. Strong bases. Strong oxidizing agents.
Hazardous decomposition products	None known based on information supplied.

11. Toxicological information

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 diarrhea. 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.
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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) 50-01-1	= 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 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.
Other adverse effects	No information available.
Interactive effects	No information available.

12. Ecological information

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

Persistence and degradability No information available.

Bioaccumulation**Component Information**

Chemical name	Partition coefficient
Guanidine, hydrochloride (1:1) 50-01-1	-1.7

Other adverse effects No information available.

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.

14. Transport information

DOT Not regulated

TDG Not regulated

MEX Not regulated

IATA Not regulated

IMDG Not regulated

15. Regulatory information

International Inventories Contact supplier for inventory compliance status

US Federal Regulations**SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Water	-	-	X

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U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA	Health hazards 2	Flammability 0	Instability 0	Special hazards -
HMIS	Health hazards 2	Flammability 0	Physical hazards 0	Personal protection X

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

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)
 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 date 15-Sep-2023
Revision Note New Safety Data Sheet.

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