

SAFETY DATA SHEET

Revision date 15-Sep-2023

Revision Number 1.1

Section 1: Identification

Product identifier

Product Name Exact Diagnostics BKV Urine LOD

Catalogue Number(s) BKVULOD

Other means of identification

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic

Uses advised against No information available

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 Pty Ltd
189 Bush Road
Albany Auckland
New Zealand

Technical Service

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Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC New Zealand: 64-98010034

GHS Classification

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

Label elements



Signal word

Warning

Hazard statements

Harmful if swallowed
Causes skin irritation
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/clothing and eye/face protection

Eyes

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

Skin

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

Ingestion

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.
Contains human source material and / or potentially infectious components

Section 3: Composition/information on ingredients

The product contains no substances which at their given concentration, are considered to be hazardous to health

Chemical name	CAS No	Weight-%
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.
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 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 with soap and water.
Ingestion	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.
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: Fire-fighting measures

Suitable 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.

Specific hazards arising from the chemical

Specific hazards arising from the chemical No information available.

Special protective actions for fire-fighters

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

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 Use: Disinfectant. Clean contaminated surface thoroughly.

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).

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.

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

<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	
Vapour pressure	No data available	None known
Vapour density	No data available	None known
Relative density	No data available	None known
Water solubility	No data available	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	No information available.	
Oxidising properties	No information available.	

Other information

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
Particle characteristics	No information available

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.
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Sensitivity to static discharge	None.
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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.
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Incompatible materials

Incompatible materials	Strong acids. Strong bases. Strong oxidising agents.
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Hazardous decomposition products

Hazardous decomposition products	None known based on information supplied.
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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. 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

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

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.

Data used to identify the health effects

Refer to Section 16 for Key literature references and sources for data used to compile the SDS.

Section 12: Ecological information

Ecotoxicity**Aquatic 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.

Terrestrial ecotoxicity

There is no data for this product.

Persistence and degradability No information available.

Bioaccumulative potential

Bioaccumulation There is no data for this product.

Mobility in soil

Mobility No information available.

Other adverse effects

No information available.

Section 13: Disposal considerations

Waste treatment methods

Waste from residues/unused products

Dispose of product in packaging in a way that is consistent with the EPA Consolidation 30 April 2021 of the Hazardous Substances (Disposal) Notice 2017 and the Act.
Treat the substance using a method that changes the characteristics or composition of the substance so that the substance is no longer a hazardous substance; or export the substance from New Zealand as waste.
Substances which are hazardous to human health or corrosive to metals – may be discharged into the environment if a tolerable exposure limit has been set for the substance (or a component of that substance); and the discharge does not, after reasonable mixing, result in the concentration of the substance in an environmental medium exceeding the tolerable exposure limit. If there is no tolerable exposure limit for the substance, then it may only be discharged into the environment if the substance is very rapidly converted to substances that are not hazardous substances.
Dispose of in accordance with local regulations.
Dispose of waste in accordance with environmental legislation.

Contaminated packaging

For packages that have been in direct contact with hazardous substances, the person must ensure that the package is rendered incapable of containing any substance. It must be disposed of in a manner that is consistent with the requirements for disposal of the substance that it contained, taking into account the material the package is manufactured from.
Packages may only be reused or recycled if:
- the substance has a physical hazard other than corrosive to metal, and has been treated to remove any residual contents of the hazardous substance;
- or for substances that have a health or environmental hazard, or corrosive to metal, the contents of the residue in the package are below the threshold for the substance to be classified as hazardous in the Hazardous Substances (Hazard Classification) Notice 2020.

Section 14: Transport information

IATA Not regulated

IMDG Not regulated

Transport in bulk according to Annex II of MARPOL and the IBC Code

No information available

Special precautions for user

Please refer to the applicable dangerous goods regulations for additional information

Section 15: Regulatory information

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

National regulations

EPA New Zealand HSNO approval code or group standard To be determined

National regulations

There are no applicable tolerable exposure limits or environmental exposure limits according to the EPA Controls for Hazardous Substances

Certified handlers, tracking and controlled substance license requirements

Certified handlers are required for some substances. This includes substances requiring a controlled substance license, and most explosives, vertebrates toxic agents, and certain fumigants. Acutely toxic substances which are a Category 1 or 2, such as pesticides also require Certified handlers. Please check the Health and Safety at Work Act 2015 for further information

Tracking is required for some highly hazardous substances. These substances need to be under the control of an appropriately trained person or appropriately secured. Please check the Health and Safety at Work Act 2015 for further information

Controlled substance licenses are required to possess certain explosives, vertebrate toxic agents and fumigants. See Part 7 of the Health and Safety at Work Regulation 2017 for more information

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

International Inventories

NZIoC	Contact supplier for inventory compliance status.
TSCA	Contact supplier for inventory compliance status.
DSL/NDSL	Contact supplier for inventory compliance status.
EINECS/ELINCS	Contact supplier for inventory compliance status.
ENCS	Contact supplier for inventory compliance status.
IECSC	Contact supplier for inventory compliance status.
KECL	Contact supplier for inventory compliance status.
PICCS	Contact supplier for inventory compliance status.
AICS	Contact supplier for inventory compliance status.

Legend:

NZIoC - New Zealand Inventory of Chemicals
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

Section 16: Other information

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) (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

Disclaimer

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End of Safety Data Sheet