

SAFETY DATA SHEET

Revision date 15-Sep-2023

Revision Number 1.1

Section 1: Identification

Product identifier

Product Name Exact Diagnostics SARS-CoV-2, Flu, RSV Run Control

Catalogue Number(s) COVFLU, COVFLUNEG

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 +64 9 415 2280 or 0508 805 500
sales.nz@bio-rad.com

Emergency telephone number

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

GHS Classification

Skin sensitisation

Category 1

Label elements



Signal word

Warning

Hazard statements

May cause an allergic skin reaction

Precautionary Statements - Prevention

Avoid breathing dust/fume/gas/mist/vapours/spray
Contaminated work clothing must not be allowed out of the workplace
Wear protective gloves/clothing and eye/face protection

Skin

IF ON SKIN: Wash with plenty of water and soap

If skin irritation or rash occurs: Get medical advice/attention
Take off all contaminated clothing and wash it before reuse

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

No information available.

Contains human source material and / or potentially infectious components

Section 3: Composition/information on ingredients

Chemical name	CAS No	Weight-%
Trade secret	-	10 - 20
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	55965-84-9	0.001 - 0.01

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.
Inhalation	Remove to fresh air.
Eye contact	Contains human source material and / or potentially infectious components. Call a doctor. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Skin contact	Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a doctor.
Ingestion	Contains human source material and / or potentially infectious components. Call a doctor.

Most important symptoms and effects, both acute and delayed

Symptoms	Itching. Rashes. Hives.
-----------------	-------------------------

Indication of any immediate medical attention and special treatment needed

Note to doctors	May cause sensitisation in susceptible persons. Treat symptomatically. 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 Product is or contains a sensitiser. May cause sensitisation by skin contact.

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. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

For emergency responders Use personal protection recommended in Section 8.

Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

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. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash it before reuse.

General hygiene considerations 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. Store according to product and label instructions.

Incompatible materials None known based on information supplied.

Section 8: Exposure controls/personal protection

Control parameters

Exposure Limits

Chemical name	New Zealand	Australia	ACGIH TLV	United Kingdom
Trade secret	TWA: 10 mg/m ³	TWA: 10 mg/m ³	TWA: 10 mg/m ³	TWA: 10 mg/m ³ STEL: 20 mg/m ³

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.

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 No information available

Colour clear

Odour No information available.

Odour threshold No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH		None known
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	None known
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.
------------	---------------------------

Chemical stability

Stability	Stable under normal conditions.
-----------	---------------------------------

Explosion data

Sensitivity to mechanical impact	None.
----------------------------------	-------

Sensitivity to static discharge	None.
---------------------------------	-------

Possibility of hazardous reactions

Possibility of hazardous reactions	None under normal processing.
------------------------------------	-------------------------------

Conditions to avoid

Conditions to avoid	None known based on information supplied.
---------------------	---

Incompatible materials

Incompatible materials	None known based on information supplied.
------------------------	---

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.
------------	---

Eye contact	Specific test data for the substance or mixture is not available.
-------------	---

Skin contact	May cause sensitisation by skin contact. Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components).
--------------	---

Ingestion	Specific test data for the substance or mixture is not available.
-----------	---

Symptoms	Itching. Rashes. Hives.
----------	-------------------------

Acute toxicity

Numerical measures of toxicity

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

ATEmix (oral) 62,305.30 mg/kg
ATEmix (dermal) 62,305.30 mg/kg

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Trade secret	= 29700 mg/kg (Rat)	-	-
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	= 53 mg/kg (Rat)	= 87.12 mg/kg (Rabbit)	-

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

Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
Respiratory or skin sensitisation	May cause an allergic skin reaction.
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

Component Information

Chemical name	Partition coefficient
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	0.7

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 Significant changes throughout SDS. Review all sections.

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

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