

This safety data sheet was created pursuant to the requirements of:
US OSHA Hazard Communication Standard (29 CFR 1910.1200) and Canada WHMIS
2015 which includes the amended Hazardous Products Act (HPA) and the Hazardous
Products Regulation (HPR)

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Revision Number 1

1. Identification**Product identifier****Product Name** VITROS Immunodiagnostic Products Syphilis Controls**Other means of identification****Product Code(s)** 6177335**Synonyms** None**Recommended use of the chemical and restrictions on use****Recommended use** In vitro diagnostic**Restrictions on use** No information available**Details of the supplier of the safety data sheet****Supplier Address**

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626-5101

Customer Service Telephone

US/Mexico –
English: 1 (800) 828-6316
Spanish: 1 (800) 828-6316

Canada -
English: 1 (800) 616-9000
French: 1 (800) 211-4911

Emergency telephone number**Emergency Telephone**

English: 1 (800) 421-3311
Spanish: 1 (800) 421-3311
French: 1 (800) 421-3311

Transportation Emergency Telephone

US/Canada: 1 (800) 424-9300
International and Maritime: +1 (703) 527-3887

2. Hazard(s) identification**Classification**

Skin sensitization

Category 1A

Appearance Clear liquid**Physical state** Liquid**Odor** None

Label elements

Warning

Hazard statements

May cause an allergic skin reaction



Precautionary Statements - Prevention

Avoid breathing dust, fume, gas, mist, vapors and spray
Contaminated work clothing must not be allowed out of the workplace
Wear protective gloves

Skin

IF ON SKIN: Wash with plenty of water and soap
If skin irritation or rash occurs: Get medical advice and attention
Wash contaminated clothing before reuse

Precautionary Statements - Disposal

Dispose of contents and container to an approved waste disposal plant

Other information

This product contains human blood derivatives. No known test method can offer complete assurance that products derived from human blood will not transmit infectious agents. Therefore, all blood derivatives should be considered potentially infectious. It is recommended that these reagents be handled using established good laboratory working practices. Harmful to aquatic life.

3. Composition/information on ingredients

Substance

Not applicable.

Mixture

Chemical name	CAS No	Weight-%	Hazardous Material Information Review Act registry number (HMIRA registry #)	Date HMIRA filed and date exemption granted (if applicable)
2-Methyl-3-isothiazolone	2682-20-4	0.095	-	-

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

Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.
Consult a physician.

Skin contact	Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a physician.
Ingestion	Rinse mouth. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Call a physician.

Most important symptoms and effects, both acute and delayed

Symptoms	Itching. Rashes. Hives.
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Indication of any immediate medical attention and special treatment needed

Note to physicians	May cause sensitization in susceptible persons. Treat symptomatically.
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5. Fire-fighting measures

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
Specific hazards arising from the chemical	Product is or contains a sensitizer. May cause sensitization by skin contact.
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	Handle all blood and materials in contact with blood as if capable of transmitting infectious agents. It is recommended that blood and materials in contact with blood be handled using established good laboratory practices. 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.
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Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Pick up and transfer to properly labeled containers.

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
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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 before reuse.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep container tightly closed in a dry and well-ventilated place. Store according to 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.

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.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Liquid
Appearance Clear liquid
Color Colorless
Odor None
Odor threshold No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	7.0 - 7.4	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	
Vapor pressure	No data available	None known
Vapor 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	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	None under normal use conditions.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	Heat.
Incompatible materials	None known based on information supplied.
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.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	May cause sensitization 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 related to the physical, chemical and toxicological characteristics

Symptoms	Itching. Rashes. Hives.
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Acute toxicity

Numerical measures of toxicity

Based on available data, the classification criteria are not met

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
2-Methyl-3-isothiazolone 2682-20-4	232 - 249 mg/kg (Rat - Male) = 120 mg/kg (Rat - Female)	= 200 mg/kg (Rabbit)	= 0.11 mg/L (Rat) 4 h

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 sensitization	May cause sensitization by skin contact.
Germ cell mutagenicity	No information available.
Carcinogenicity	Contains no ingredients above reportable quantities listed as a carcinogen.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.

12. Ecological information

Ecotoxicity	Harmful to aquatic life.
Persistence and degradability	No information available.
Bioaccumulation	No information available.

Component Information

Chemical name	Partition coefficient
2-Methyl-3-isothiazolone 2682-20-4	-0.26

Mobility in soil	No information available.
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
IATA	Not regulated
IMDG	Not regulated

15. Regulatory information

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

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

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

This product does not contain any substances regulated under applicable state right-to-know regulations

16. Other information

<u>NFPA</u>	Health hazards 2	Flammability 0	Instability 0	Special hazards -
<u>HMIS</u>	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) (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)
 Japan GHS Classification
 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

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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