Ortho Clinical Diagnostics

SAFETY DATA SHEET

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)

Issuing Date 23-Feb-2022 **Revision Date** 23-Feb-2022 **Revision Number** 1

1. Identification

Product identifier

Product Name VITROS Immunodiagnostic Products Total β-hCG II Assay Reagent

Other means of identification

Product Code(s) 6199334AR

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
USA

Manufacturer Address
Ortho-Clinical Diagnostics
Felindre Meadows
Pencoed
Bridgend
CF35 5PZ
United Kingdom

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 Colorless to yellow aqueous solution **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

Precautionary Statements - Response

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
Toxic to aquatic life with long lasting effects. Toxic to aquatic life. This product contains animal blood derivatives. No known test method can offer complete assurance that products derived from animal 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.

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)
Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone	55965-84-9	0.03	-	-

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 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.

Effects of Exposure No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians May cause sensitization in susceptible persons. Treat symptomatically.

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 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. 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.

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 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	Colorless to yellow aqueous solution
Color	Colorless to yellow
Odor	None
Odor threshold	No information available

Property	**Values**	**Remarks • Method**
pH	6.6	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.

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
Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone 55965-84-9	= 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 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 Toxic to aquatic life. Toxic to aquatic life with long lasting effects.

Persistence and degradability No information available.

Bioaccumulation No information available.

Chemical name	Partition coefficient
Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone 55965-84-9	0.7

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

Note: This package is shipped in accordance with ADR Special Provision 375, IATA A197 & IMDG 2.10.2.7. These substances when carried in single or combination packaging containing a net quantity per single or inner packaging of 5L/5kg or less, are not subject to any other provisions of the regulations provided the packaging meets the general provisions of the applicable regulations

DOT
Notes Not regulated
Special Provisions Special Provision 49CFR 171.4(c)(2)

TDG
UN number or ID number UN3082 – Limited Quantity

IATA
UN number or ID number UN3082 – Exempt as per note above

IMDG
UN number or ID number UN3082 – Exempt as per note above
Special Provisions Special Provision 2.10.2.7

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

International Inventories

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

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
+	Sensitizers		

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

Issuing Date	23-Feb-2022
Revision Date	23-Feb-2022
Revision Note	Initial Release.

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