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 HRP Conjugate Reagent

**Other means of identification**

**Product Code(s)** 6199334CJ

**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** | 6.0 | 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**

| Chemical name | New Jersey | Massachusetts | Pennsylvania |
|---|---|---|---|
| Potassium ferricyanide<br>13746-66-2 | X | - | X |

## 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**

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**End of Safety Data Sheet**