SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: US OSHA Hazard Communication Standard 2024 (29 CFR 1910.1200) and Canada Hazardous Products Act (HPA) and the Hazardous Products Regulation (HPR), as amended

Issuing Date 29-Nov-2023 **Revision date** 09-Dec-2025 **Revision Number** 2

1. Identification

Product identifier

Product Name VITROS Immunodiagnostic Products Anti-HCV Calibrators

Other means of identification

Product Code(s) OCDUK6801326

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

Customer Service
1 (800) 828-6316
http://www.quidelortho.com/global/en/contact-us/

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

Emergency telephone number

Emergency Telephone
CHEMTREC: +1-703-527-3887 (INTERNATIONAL)
1-800-424-9300 (NORTH AMERICA)

2. Hazard(s) identification

Classification of the substance or mixture

Skin sensitization	Category 1A

Appearance Colorless, 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.
Wear protective gloves.
Contaminated work clothing must not be allowed out of the workplace.

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

Precautionary Statements - Disposal
Dispose of contents and container in accordance with local, regional, national, and international regulations as applicable.

Hazards classified under paragraph (d)(1)(ii) of 1910.1200
No information available.

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

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 Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Call a physician.

Most important symptoms and effects, both acute and delayed

Symptoms Itching. Rashes. Hives.

Effects of Exposure See Section 11 for additional Toxicological Information.

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 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.

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.

General hygiene considerations Do not eat, drink or smoke when using this product. Wash hands before breaks and after work.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool 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.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance Colorless, aqueous solution

Physical state	Liquid
Color	Colorless
Odor (includes odor threshold)	None

Property	Values	Remarks • Method
Melting point / freezing point	No data available	None known
Boiling point (or initial boiling point or boiling range)	No data available	None known
Flammability	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	
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
SADT (°C)		None known
pH	No data available	None known
pH (as aqueous solution)	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Solubility	No data available	None known
Water solubility	No data available	None known
Partition coefficient n-octanol/water (log value)	No data available	None known
Vapor pressure (includes evaporation rate)	No data available	None known
Evaporation rate	No data available	None known
Density and/or relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Relative vapor density	No data available	None known
Particle characteristics		None known
Particle Size	No data available	
Particle Size Distribution	No data available	

Other information

Molecular weight	No information available
VOC content	No information available
Softening point	No information available

Information with regard to physical hazard classes

Explosives	
Explosive properties	No information available
Oxidizing properties	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 an allergic skin reaction.

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 with long lasting effects.

Chemical name	Fish	Crustacea	Algae/aquatic plants	Toxicity to microorganisms
Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone	LC50: =1.6mg/L (96h, Oncorhynchus mykiss)	EC50: =4.71mg/L (48h, Daphnia magna) EC50: 0.12 - 0.3mg/L (48h, Daphnia magna) EC50: 0.71 - 0.99mg/L (48h, Daphnia magna)	EC50: 0.11 - 0.16mg/L (72h, Pseudokirchneriella subcapitata) EC50: 0.03 - 0.13mg/L (96h, Pseudokirchneriella subcapitata)	-

Persistence and degradability No information available.

Bioaccumulative potential

Chemical name	Partition coefficient	Bioconcentration factor (BCF)	Trophic magnification factor (TMF)
Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone	0.7	54	-

Mobility in soil No information available.

Other adverse effects No information available.

13. Disposal considerations

Disposal 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 Not regulated

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

TSCA Exempt.

DSL/NDSL Exempt.

Legend:
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

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).

CAA (Clean Air Act)
This product does not contain any substances regulated as pollutants pursuant to Clean Air Act (CAA).

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
List may include phrases which are not applicable to this product

ACGIH	American Conference of Governmental Industrial Hygienists
ADN	Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Europe)
ADR	Agreement concerning the International Carriage of Dangerous Goods by Road (Europe)
AIIC	Australian Inventory of Industrial Chemicals
ATE	Acute Toxicity Estimate
ASTM	American Society for the Testing of Materials
bar	Biological Reference Values for Chemical Compounds in the Work Area
BAT	Biological tolerance values for occupational exposure
BEL	Biological exposure limits
bw	Body weight
Ceiling	Maximum limit value
CMR	Carcinogen, Mutagen or Reproductive Toxicant
DOT	Department of Transportation (United States)
DSL	Domestic Substances List (Canada)
EmS	Emergency Schedule
ENCS	Existing and New Chemical Substances (Japan)
EPA	U.S. Environmental Protection Agency
GHS	Globally Harmonized System
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IBC	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
ICAO	International Civil Aviation Organization
IECSC	Inventory of Existing Chemical Substances in China
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
ISO	International Organization for Standardization
KECI	Korean Existing Chemicals Inventory
LC50	Lethal Concentration to 50% of a test population
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)
MARPOL	International Convention for the Prevention of Pollution from Ships
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
n.o.s.	Not Otherwise Specified
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NOELR	No Observable Effect Loading Rate
NTP	National Toxicology Program (United States)
NZIoC	New Zealand Inventory of Chemicals
OECD	Organization for Economic Cooperation and Development
OEL	Occupational exposure limits
OSHA	Occupational Safety and Health Administration of the US Department of Labor
PBT	Persistent, Bioaccumulative and Toxic substance
PICCS	Philippines Inventory of Chemicals and Chemical Substances
PMT	Persistent, Mobile and Toxic
PPE	Personal protective equipment

QSAR	Quantitative Structure Activity Relationship
RID	Agreement concerning the International Carriage of Dangerous Goods by Rail (Europe)
SADT	Self-Accelerating Decomposition Temperature
SAR	Structure-activity relationship
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
SL	Surface Limit
STEL	Short Term Exposure Limit
STOT RE	Specific target organ toxicity - Repeated exposure
STOT SE	Specific target organ toxicity - Single exposure
TCSI	Taiwan Chemical Substance Inventory
TDG	Transport of Dangerous Goods (Canada)
TSCA	Toxic Substances Control Act (United States)
TWA	Time-Weighted Average
UN	United Nations
VOC	Volatile organic compounds
vPvB	Very Persistent and Very Bioaccumulative
vPvM	Very Persistent and Very Mobile
As	Allergenic substance
DS	Dermal Sensitizer
Ot	Ototoxicant
pOt	Ototoxicant - potential to cause hearing disorders
PS	Photosensitizer
RS	Respiratory Sensitizer
S	Sensitizer
poS	Sensitizer - capable of causing occupational asthma
Sa	Simple asphyxiant
Sd	Skin designation
pSd	Skin designation - potential for cutaneous absorption
Sdv	Skin designation - vacated
Sk	Skin notation
dSk	Skin notation - danger of cutaneous absorption
pSk	Skin notation - potential for cutaneous absorption

Key literature references and sources for data used to compile the SDS

U.S. Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
U.S. 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)
U.S. National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
International Organization for Economic Co-operation and Development (OECD) Environment, Health, and Safety Publications
International Organization for Economic Co-operation and Development (OECD) High Production Volume Chemicals Program
International Organization for Economic Co-operation and Development (OECD) Screening Information Data Set
United Nations World Health Organization (WHO)

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Revision Note	Updated format.

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