Ortho Clinical Diagnostics

SAFETY DATA SHEET

Issuing Date 05-Aug-2015 Revision Date 02-Mar-2016 Revision Number 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

GHS product identifier

Product Name VITROS Immunodiagnostic Products PSA HRP Conjugate Reagent

Other means of identification

Product Code(s) OCDUK6801756CJ

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended Use Reagent

Uses advised against No information available

Supplier's details

Supplier Address

Ortho-Clinical Diagnostics

Felindre Meadows

Pencoed Bridgend CF35 5PZ

United Kingdom

Customer service telephone: (800) 421-3311

Emergency telephone number

Emergency Telephone

Number

Regional Emergency Telephone Number:

French 03 88 65 47 33 Spanish 900 97 33 25

Transportation Emergencies:

US Telephone Number: (800) 424-9300

International and Maritime Telephone Number: +1 (703) 527-3887

2. HAZARDS IDENTIFICATION

Classification

This product is considered hazardous by the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

Skin Sensitization	Category 1
Reproductive Toxicity	Category 2

GHS Label elements, including precautionary statements

Emergency Overview

Signal Word

Warning

Hazard Statements

- May cause an allergic skin reaction
- Suspected of damaging fertility or the unborn child



Appearance Colorless. Aqueous solution. Physical State Liquid.

Odor None.

Precautionary Statements

Prevention

- Avoid breathing dust/fume/gas/mist/vapors/spray.
- Contaminated work clothing should not be allowed out of the workplace.
- · Wear protective gloves.
- Obtain special instructions before use.
- Do not handle until all safety precautions have been read and understood.
- Use personal protective equipment as required.

General Advice

- Specific treatment (see supplemental instructions on the administration of antidotes on this label)
- If exposed or concerned: Get medical attention/advice
- Specific treatment is urgent (see supplemental first aid instructions on this label)

Skin

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

Storage

· Store locked up.

Disposal

• Dispose of contents/container to an approved waste disposal plant.

Hazard Not Otherwise Classified (HNOC)

Not applicable.

Other information

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. May cause an allergic skin reaction

<1% of the mixture consists of ingredient(s) of unknown toxicity.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %
Bovine Serum Albumin (BSA)	9048-46-8	3
2-Chloroacetamide	79-07-2	0.5

4. FIRST AID MEASURES

Description of necessary first-aid measures

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Reagent

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get **Eye Contact**

medical attention if irritation occurs.

Skin Contact Wash off immediately with plenty of water for at least 15 minutes. In the case of skin

irritation or allergic reactions see a physician.

Inhalation IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position

comfortable for breathing. Get medical attention.

Ingestion Rinse mouth. Do NOT induce vomiting. Drink plenty of water. Never give anything by mouth

to an unconscious person. Get medical attention.

Most important symptoms/effects, acute and delayed

Most Important Symptoms/Effects May cause allergic skin reaction. Itching. Hives. Rashes.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to Physician 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 None

Specific Hazards Arising from the Chemical

No information available.

Explosion Data

Sensitivity to Mechanical Impact Sensitivity to Static Discharge

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

None.

None.

Personal precautions, protective equipment and emergency procedures

Personal Precautions Use personal protective equipment. Do not touch damaged containers or spilled material

unless wearing appropriate protective clothing. Avoid contact with skin, eyes and clothing.

Environmental Precautions

Environmental Precautions Prevent further leakage or spillage if safe to do so.

Methods and materials for containment and cleaning up

Methods for Containment Wipe up with absorbent material (e.g. cloth, fleece). Pick up and transfer to properly labeled

containers.

Methods for Cleaning Up Clean contaminated surface thoroughly. Clean with disinfectants.

7. HANDLING AND STORAGE

Precautions for safe handling

Reagent

Handle in accordance with good industrial hygiene and safety practice. Wear personal Handling

protective equipment. Refer to Section 8. Avoid contact with skin, eyes and clothing. Wash

thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Keep at temperatures between 15 °C and 30 °C. Do not freeze. Storage

None known. **Incompatible Products**

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product does not contain any hazardous materials with occupational exposure limits

established by the region specific regulatory bodies.

Appropriate engineering controls

Showers **Engineering Measures**

Eyewash stations Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/Face Protection If splashes are likely to occur, wear: Safety glasses with side-shields.

Protective gloves. Lightweight protective clothing. **Skin and Body Protection**

Respiratory Protection None required under normal usage.

Handle in accordance with good industrial hygiene and safety practice. **Hygiene Measures**

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State Liquid. **Appearance** Colorless. Aqueous solution. Odor None. **Odor Threshold** No information available.

Property **Values** Remarks/ - Method Not applicable None known No data available **Melting Point/Range** None known **Boiling Point/Boiling Range** No data available None known Flash Point Not determined. None known **Evaporation rate** No data available None known Flammability (solid, gas) No data available None known Flammability Limits in Air No data available upper flammability limit

lower flammability limit No data available **Vapor Pressure** No data available None known **Vapor Density** No data available None known No data available **Specific Gravity** None known No data available None known Water Solubility No data available None known Solubility in other solvents Partition coefficient: n-octanol/waterNo data available None known No data available **Autoignition Temperature** None known No data available None known **Decomposition Temperature Viscosity** No data available None known

Not flammable Flammable Properties

Explosive Properties No data available **Oxidizing Properties** No data available

Reagent

Other information

VOC Content (%) No data available

10. STABILITY AND REACTIVITY

Reactivity

Not reactive under normal conditions.

Chemical stability

Stable under recommended storage conditions.

Possibility of hazardous reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to avoid

Heat.

Incompatible materials

None known.

Hazardous decomposition products

None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation May cause irritation. Acute or repeated inhalation of aerosol or mist may cause a systemic

allergic reaction.

Eye Contact May cause slight irritation.

Skin Contact May cause sensitization by skin contact. **Ingestion** Not expected to be toxic following ingestion.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
2-Chloroacetamide	= 138 mg/kg (Rat)	-	-
Chloramphenicol	= 2500 mg/kg (Rat)	-	-

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling

of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain, or flushing

Allergic skin reactions or irritation.

Delayed and immediate effects and also chronic effects from short and long term exposure

Sensitization May cause an allergic skin reaction. May cause sensitization by skin contact.

Mutagenic Effects No information available.

Carcinogenicity Contains no ingredients above reportable quantities listed as a carcinogen.

Reproductive Toxicity Contains a known or suspected reproductive toxin. In animal studies, adverse reproductive

effect(s) include: Decrease in spermatogenesis, testicular changes and sterility.

STOT - single exposure
STOT - repeated exposure
No information available.
No information available.

Target Organ Effects Skin.

Aspiration Hazard No information available.

Numerical measures of toxicity - Product

Acute Toxicity <1% of the mixture consists of ingredient(s) of unknown toxicity.

The following values are calculated based on chapter 3.1 of the GHS document: LD50 Oral >5000 mg/kg; (ATE); Acute toxicity estimate

12. ECOLOGICAL INFORMATION

Ecotoxicity

The environmental impact of this product has not been fully investigated. Contains a substance which is harmful to the aquatic environment with long lasting effects at very low concentrations.

2-chloroacetamide:

EC50/48h/Daphnia magna = 14 mg/l LC50/48h/goldfish = 21.1 mg/l LC50/96h/goldfish = 19.8 mg/l

Persistence and Degradability No information available.

Bioaccumulation No information available.

Other Adverse Effects
No information available.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods This material, as supplied, is not a hazardous waste according to Federal regulations (40

CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local

regulations for additional requirements.

Contaminated Packaging Do not re-use empty containers.

14. TRANSPORT INFORMATION

DOT Not regulated

TDG Not regulated.

IATA Not regulated.

IMDG/IMO Not regulated.

15. REGULATORY INFORMATION

International Inventories

TSCA Exempt

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DSL Exempt
NDSL Exempt

Legend

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

U.S. Federal Regulations

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

Acute Health Hazard Yes
Chronic Health Hazard Yes
Fire Hazard No
Sudden Release of Pressure Hazard No
Reactive Hazard No

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.

U.S. State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals:

Chemical Name	CAS-No	California Prop. 65
Chloramphenicol	56-75-7	Carcinogen

U.S. State Right-to-Know Regulations

This product does not contain any substances above threshold limits that are regulated by state right-to-know.

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. OTHER INFORMATION					
NFPA	Health Hazard 2	Flammability 0	Instability 0	Physical and Chemical Hazards -	
<u>HMIS</u>	Health Hazard 2*	Flammability 0	Physical Hazard 0	Personal Protection X	

^{*}Indicates a chronic health hazard.

Prepared By Product Stewardship

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Revision Note (M)SDS sections updated. 1.

General Disclaimer

The information provided on this SDS 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 guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as 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 material or in any process, unless specified in the text.

End of Safety Data Sheet