Ortho Clinical Diagnostics

SAFETY DATA SHEET

Issuing Date 01-Jun-2015 **Revision Date** 01-Mar-2016 **Revision Number** 1

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

GHS product identifier

Product Name **VITROS Immunodiagnostic Products PSA Calibrators**

Other means of identification

Product Code(s) **OCDUK1933027**

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended Use Diagnostic agent

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

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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

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.
<5% of the mixture consists of ingredient(s) of unknown toxicity.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %
2-Chloroacetamide	79-07-2	0.5

4. FIRST AID MEASURES

Description of necessary first-aid measures

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get 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: 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. Hives. Itching. 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 No information available.

Specific Hazards Arising from the Chemical
No information available.

Explosion Data
Sensitivity to Mechanical Impact None.
Sensitivity to Static Discharge None.

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

Personal precautions, protective equipment and emergency procedures

Personal Precautions Ensure adequate ventilation. Wear protective gloves/clothing and eye/face protection. Avoid contact with skin, eyes and clothing. 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.

Environmental Precautions

Environmental Precautions Do not allow material to contaminate ground water system.

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 with disinfectants. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Wear personal protective equipment. Refer to Section 8. Wash thoroughly after handling.

Conditions for safe storage, including any incompatibilities

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

Incompatible Products None known based on information supplied.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Phenol 108-95-2	TWA: 5 ppm S*	TWA: 5 ppm TWA: 19 mg/m³ (vacated) TWA: 5 ppm (vacated) TWA: 19 mg/m³ (vacated) S* S*	IDLH: 250 ppm Ceiling: 15.6 ppm 15 min Ceiling: 60 mg/m³ 15 min TWA: 5 ppm TWA: 19 mg/m³

Appropriate engineering controls

Engineering Measures Showers
Eyewash stations
Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/Face Protection Safety glasses with side-shields.
Skin and Body Protection Long sleeved clothing. Impervious gloves.
Respiratory Protection None required under normal usage.

Hygiene Measures 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.
Odor None.
Appearance Colorless, Aqueous solution.
Odor Threshold No information available.

Property	Values	Remarks/ - Method
pH	No data available	None known
Melting Point/Range	No data available	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		
upper flammability limit	No data available	
lower flammability limit	No data available	
Vapor Pressure	No data available	None known
Vapor Density	No data available	None known
Specific Gravity	No data available	None known
Water Solubility	No data available	None known
Solubility in other solvents	No data available	None known
Partition coefficient: n-octanol/water	No data available	None known
Autoignition Temperature	No data available	None known
Decomposition Temperature	No data available	None known
Viscosity	No data available	None known

Flammable Properties Not flammable

Explosive Properties No data available
Oxidizing Properties No data available

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 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 The product is not expected to be toxic by inhalation. May cause irritation.
Eye Contact May cause irritation.
Skin Contact May cause sensitization by skin contact. May cause irritation.
Ingestion Not expected to be toxic following ingestion. May cause irritation to the gastrointestinal tract.

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

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Allergic skin reactions or irritation. 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.

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

Sensitization May cause sensitization by skin contact.
Mutagenic Effects No information available.
Carcinogenicity

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 No information available.
STOT - repeated exposure No information available.
Target Organ Effects Skin. Eyes. Reproductive system.
Aspiration Hazard No information available.

Numerical measures of toxicity - Product
Acute Toxicity <5% 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; 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.

Ozone Not applicable

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.

Chemical Name	RCRA	RCRA - Basis for Listing	RCRA - D Series Wastes	RCRA - U Series Wastes
Phenol - 108-95-2	U188	Included in waste streams: F039, K001, K022, K087		U188

14. TRANSPORT INFORMATION

DOT Not regulated

TDG Not regulated

IATA Not regulated

IMDG/IMO Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA	Exempt
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 does not contain any Proposition 65 chemicals.

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** -
HMIS	**Health Hazard** 2*	**Flammability** 0	**Physical Hazard** 0	**Personal Protection** X

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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