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Revision Number 0

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY UNDERTAKING**GHS product identifier****Product Name** ORTHO ELISA Test System Specimen Diluent**Other means of identification****Product Code(s)** OCDUS930740/930750/933245/933275SD**Synonyms** None**Recommended use of the chemical and restrictions on use****Recommended Use** In vitro diagnostic**Uses advised against** No information available**Supplier's details****Supplier Address**Ortho-Clinical Diagnostics, Inc.
1001 US Highway 202
Raritan, NJ 08869**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

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. HAZARDS IDENTIFICATION**Classification**

Skin Sensitization	Category 1
Reproductive Toxicity	Category 2

Label Elements

Emergency Overview

Signal Word	Warning	
Hazard Statements <ul style="list-style-type: none">• May cause an allergic skin reaction• Suspected of damaging fertility or the unborn child		
		
Appearance Blue green.	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

- 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.

Physical and Health Hazards Not Otherwise Classified

Not applicable.

Other information

May cause an allergic skin reaction. 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. This product contains human blood derivatives. No known test method can offer complete assurance that products derived from human 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.

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %	Hazardous Material Information Review Act registry number (HMIRA registry #)	Date HMIRA filed and date exemption granted (if applicable)
Bovine Serum Albumin (BSA)	9048-46-8	1	-	-
2-Chloroacetamide	79-07-2	0.1	-	-

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 soap and plenty of water for at least 15 minutes while removing all contaminated clothing and shoes. 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 known

Specific Hazards Arising from the Chemical None known

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

unless wearing appropriate protective clothing. 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 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

Handling Handle in accordance with good industrial hygiene and safety practice. Wear personal protective equipment. Refer to Section 8. Avoid contact with skin, eyes and clothing. Wash thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Storage Keep at temperatures between 2 °C and 8 °C.

Incompatible Products None known

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

Engineering Measures Showers
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.
Skin and Body Protection Impervious 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.	Appearance	Blue green.
Odor	None.	Odor Threshold	No information available.

<u>Property</u>	<u>Values</u>	<u>Remarks/ - Method</u>
pH	6.4 - 6.5	None known
Melting Point/Range	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 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

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 irritation May cause sensitization by skin contact.
Ingestion	Not expected to be toxic following ingestion. May cause irritation.

Chemical Name	LD50 Oral	LD50 Dermal	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 Contains no ingredients above reportable quantities listed as a carcinogen

Reproductive Toxicity Contains a known or suspected reproductive toxin.
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

The following values are calculated based on chapter 3.1 of the GHS document:

Acute Toxicity < 1% of the mixture consists of ingredient(s) of unknown toxicity.
LD50 Oral > 5000 mg/kg; (ATE); Acute toxicity estimate
Inhalation

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.

Persistence and Degradability No information available

Bioaccumulation No information available

Other Adverse Effects
 No information available.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods Dispose of in accordance with local regulations.

Contaminated Packaging Do not re-use empty containers.

14. TRANSPORT INFORMATION

DOT Not regulated

TDG Not regulated.

MEX Not regulated
IATA Not regulated
IMDG/IMO Not regulated.

15 REGULATORY INFORMATION

International Regulations

Ozone depleting substances Not applicable
Persistent Organic Pollutants Not applicable
Hazardous Waste Not applicable
The Rotterdam Convention (Prior Informed Consent) Not applicable
International Convention for the Prevention of Pollution from Ships (MARPOL) Not applicable

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

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

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.

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

*Indicates a chronic health hazard.

Prepared By Product Stewardship

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	1-800-572-6501
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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

Ortho PRODUCT Category	Transfusion Medicine
Ortho SUB-CATEGORY Class	Diluent