Ortho Clinical Diagnostics

SAFETY DATA SHEET

Issuing Date 21-May-2019 **Revision Date** 21-May-2019 **Revision Number** 0

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

GHS product identifier

Product Name **ORTHO HCV Version 3.0 ELISA Test System Positive Control**

Other means of identification

Product Code(s) **OCDUS930750/930740PC**

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

Not classified

Label Elements

Emergency Overview

Signal Word **None**

Hazard Statements
• None

The product contains no substances which at their given concentration are considered to be hazardous to health

Appearance Straw-colored. **Physical State** Liquid. **Odor** None.

Precautionary Statements

Prevention
• None

General Advice
• None

Storage
• None

Disposal
• None

Physical and Health Hazards Not Otherwise Classified
Not applicable.

Other information
May be harmful if swallowed. May be harmful if absorbed through skin. 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)
Sodium azide	26628-22-8	0.2	-	-

4. FIRST AID MEASURES

Description of necessary first-aid measures

Eye Contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Skin Contact Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Consult a physician if necessary.

Inhalation Move to fresh air.

Ingestion Clean mouth with water and afterwards drink plenty of water. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Consult a physician.

Most important symptoms/effects, acute and delayed

Most Important Symptoms/Effects No information available

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 suitable gloves 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. See Section 12 for additional Ecological Information.

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. Sodium azide has been reported to form lead or copper azides in laboratory plumbing. These azides are potentially explosive. To prevent buildup, flush plumbing with a large volume of water while disposing of these solutions in the sink.

7. HANDLING AND STORAGE

Precautions for safe handling

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

Conditions for safe storage, including any incompatibilities

Storage Keep containers tightly closed in a dry, cool and well-ventilated place. Store according to label instructions.

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
Sodium azide 26628-22-8	Ceiling: 0.29 mg/m³ Sodium azide Ceiling: 0.11 ppm Hydrazoic acid vapor	(vacated) S* (vacated) Ceiling: 0.1 ppm HN3 (vacated) Ceiling: 0.3 mg/m³ NaN3	Ceiling: 0.1 ppm HN3 Ceiling: 0.3 mg/m³ NaN3

Chemical Name	Alberta	British Columbia	Ontario	Quebec
Sodium azide	Ceiling: 0.29 mg/m³ Ceiling: 0.11 ppm STEL: 0.3 mg/m³	Ceiling: 0.29 mg/m³ Ceiling: 0.11 ppm	CEV: 0.29 mg/m³ CEV: 0.11 ppm	Ceiling: 0.11 ppm Ceiling: 0.3 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 Straw-colored.
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	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 Sodium azide has been reported to form lead or copper azides in laboratory plumbing. These azides are potentially explosive. To prevent buildup, flush plumbing with a large volume of water while disposing of these solutions in the sink.

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	No known effect based on information supplied
Eye Contact	No known effect based on information supplied.
Skin Contact	May be harmful in contact with skin.
Ingestion	May be harmful if swallowed

Chemical Name	LD50 Oral	LD50 Dermal	Inhalation
Sodium azide	= 27 mg/kg (Rat)	= 20 mg/kg (Rabbit)	-

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available

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

Sensitization No information available
Mutagenic Effects 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
Target Organ Effects None known.
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; 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.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Sodium azide 26628-22-8		LC50 96 h: = 0.8 mg/L (Oncorhynchus mykiss) LC50 96 h: = 0.7 mg/L (Lepomis macrochirus) LC50 96 h: = 5.46 mg/L flow-through (Pimephales promelas)		

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. Empty containers should be taken to an approved waste handling site for recycling or disposal.

Component	RCRA - Halogenated Organic Compounds	RCRA - P Series Wastes	RCRA - F Series Wastes	RCRA - K Series Wastes
Sodium azide 26628-22-8 (0.2)		P105		

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, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302):

Chemical Name	Hazardous Substances RQs	Extremely Hazardous Substances RQs	RQ
Sodium azide	1000 lb.	1000 lb	RQ 1000 lb final RQ RQ 454 kg final RQ

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** 1	**Flammability** 0	**Instability** 0	**Physical and Chemical Hazards** -
HMIS	**Health Hazard** 1	**Flammability** 0	**Physical Hazard** 0	**Personal Protection** X

Prepared By Product Stewardship
23 British American Blvd.

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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	Control