

Issuing Date 28-Jul-2015

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Revision Number 1

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

**Product Code(s)** OCDEU6904623  
**Product Name** ORTHO Sera Anti-D (DVI)

**1.2. Relevant identified uses of the substance or mixture and uses advised against**

**Recommended use** In vitro diagnostic  
**Uses advised against** No information available.

**1.3. Details of the supplier of the safety data sheet**

<b>Importer</b>	<b>Manufacturer</b>	<b>Supplier</b>
Ortho-Clinical Diagnostics 1500 Boulevard Sébastien Brant B.P. 30335 67411 Illkirch CEDEX, France	ALBA BIOSCIENCE LIMITED James Hamilton Way Penicuik EH26 0BF UK	Ortho-Clinical Diagnostics, Inc. 1001 US Highway 202 Raritan, NJ 08869

For further information, please contact

**E-mail address** UK and Irish Republic - ukhotline@orthoclinicaldiagnostics.com  
 France - hotlinefrance@orthoclinicaldiagnostics.com  
 Germany - ocdtechsupport-de@orthoclinicaldiagnostics.com  
 Italy - italianhl@orthoclinicaldiagnostics.com  
 Nordic - nordichotline@orthoclinicaldiagnostics.com  
 Poland - service\_pl@pl.diasorin.com  
 Portugal - port\_ocdhotline@orthoclinicaldiagnostics.com  
 Spain - spanishhotline@orthoclinicaldiagnostics.com

**1.4. Emergency telephone number**

**Emergency Telephone** **Transportation Emergencies:**  
 US Telephone Number: (800) 424-9300  
 International and Maritime Telephone Number: +1 (703) 527-3887

**US:**  
 (800) 421-3311

**Emergency Telephone - §45 - (EC)1272/2008**

<b>Europe</b>	
	UK and Irish Republic 0 800 895963
	France 03 88 65 47 33
	Germany 0 800 181 48 97
	Italy 800 87 06 55
	Nordic 00 800 08372560
	Poland 48 (22) 223 62 65
	Portugal 0 800 833143
	Spain 900 97 33 25

For further contact details please refer to the Ortho SDS Contact Details Document available at

<https://www.orthoclinicaldiagnostics.com/en-us/home/technical-documents>

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

### 2.2. Label elements

#### Hazard statements

Not classified

### 2.3. Other hazards

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. 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.

**Endocrine Disruptor Information** This product does not contain any known or suspected endocrine disruptors.

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Not applicable

### 3.2 Mixtures

Chemical name	Weight-%	REACH registration number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sodium azide 26628-22-8	0.1	No data available	247-852-1	Acute Tox. 2 (H300) (EUH032) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)			

### Full text of H- and EUH-phrases: see section 16

#### Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATE<sub>mix</sub>) for classifying a mixture based on its components

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Sodium azide 26628-22-8	27	20			

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No.

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1907/2006 (REACH), Article 59)

## **SECTION 4: First aid measures**

### **4.1. Description of first aid measures**

<b>Inhalation</b>	Remove to fresh air.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician.
<b>Ingestion</b>	Rinse mouth. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Call a physician.

### **4.2. Most important symptoms and effects, both acute and delayed**

<b>Symptoms</b>	No information available.
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### **4.3. Indication of any immediate medical attention and special treatment needed**

<b>Note to physicians</b>	Treat symptomatically.
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## **SECTION 5: Firefighting measures**

### **5.1. Extinguishing media**

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Unsuitable extinguishing media</b>	Do not scatter spilled material with high pressure water streams.

### **5.2. Special hazards arising from the substance or mixture**

<b>Specific hazards arising from the chemical</b>	No information available.
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### **5.3. Advice for firefighters**

<b>Special protective equipment and precautions for fire-fighters</b>	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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## **SECTION 6: Accidental release measures**

### **6.1. Personal precautions, protective equipment and emergency procedures**

<b>Personal precautions</b>	Ensure adequate ventilation. 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.
<b>For emergency responders</b>	Use personal protection recommended in Section 8.

**6.2. Environmental precautions**

**Environmental precautions** See Section 12 for additional Ecological Information.

**6.3. 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. 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.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

**6.4. Reference to other sections**

**Reference to other sections** See section 8 for more information. See section 13 for more information.

**SECTION 7: Handling and storage****7.1. Precautions for safe handling**

**Advice on safe handling** Ensure adequate ventilation.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

**7.2. Conditions for safe storage, including any incompatibilities**

**Storage Conditions** Keep container tightly closed in a dry and well-ventilated place. Store according to label instructions.

**7.3. Specific end use(s)**

**Specific use(s).** No information available

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters****Exposure Limits**

Chemical name	European Union	Austria	Belgium	Bulgaria	Croatia
Sodium azide 26628-22-8	TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup> *	TWA: 0.1 mg/m <sup>3</sup> STEL 0.3 mg/m <sup>3</sup> H*	*	STEL: 0.3 mg/m <sup>3</sup> TWA: 0.1 mg/m <sup>3</sup> K*	TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup> *
Chemical name	Cyprus	Czech Republic	Denmark	Estonia	Finland
Sodium azide 26628-22-8	*	TWA: 0.1 mg/m <sup>3</sup> Ceiling: 0.3 mg/m <sup>3</sup> *	TWA: 0.1 mg/m <sup>3</sup> H*	TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup> A*	TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup> iho*
Chemical name	France	Germany	Germany MAK	Greece	Hungary
Sodium azide 26628-22-8	TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup> *	TWA: 0.2 mg/m <sup>3</sup>	TWA: 0.2 mg/m <sup>3</sup> Peak: 0.4 mg/m <sup>3</sup>	TWA: 0.1 ppm TWA: 0.3 mg/m <sup>3</sup> STEL: 0.1 ppm STEL: 0.3 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup>
Chemical name	Ireland	Italy	Italy REL	Latvia	Lithuania
Sodium azide	TWA: 0.1 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup>	Ceiling: 0.29 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup>	*

26628-22-8	STEL: 0.3 mg/m <sup>3</sup> Sk*	STEL: 0.3 mg/m <sup>3</sup> pelle*	Ceiling: 0.11 ppm	STEL: 0.3 mg/m <sup>3</sup> *	TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup>
Chemical name	Luxembourg	Malta	Netherlands	Norway	Poland
Sodium azide 26628-22-8	* STEL: 0.3 mg/m <sup>3</sup> TWA: 0.1 mg/m <sup>3</sup>	* STEL: 0.3 mg/m <sup>3</sup> TWA: 0.1 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup> H*	TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup>	STEL: 0.3 mg/m <sup>3</sup> TWA: 0.1 mg/m <sup>3</sup> *
Chemical name	Portugal	Romania	Slovakia	Slovenia	Spain
Sodium azide 26628-22-8	TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup> Ceiling: 0.29 mg/m <sup>3</sup> Ceiling: 0.11 ppm P*	TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup> *	TWA: 0.1 mg/m <sup>3</sup> * Ceiling: 0.3 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup> *	TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup> vía dérmica*
Chemical name	Sweden		Switzerland		United Kingdom
Sodium azide 26628-22-8	NGV: 0.1 mg/m <sup>3</sup> Bindande KGV: 0.3 mg/m <sup>3</sup>		TWA: 0.2 mg/m <sup>3</sup> STEL: 0.4 mg/m <sup>3</sup>		TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup> Sk*

**Biological occupational exposure limits** This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

**Derived No Effect Level (DNEL)** No information available.

**Predicted No Effect Concentration (PNEC)** No information available.

## 8.2. Exposure controls

### Personal protective equipment

**Eye/face protection** No special protective equipment required.

**Skin and body protection** No special protective equipment required.

**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.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

**Environmental exposure controls** No information available.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

<b>Physical state</b>	Liquid
<b>Appearance</b>	White to Straw-colored liquid
<b>Color</b>	White to Straw-colored
<b>Odor</b>	No information available.
<b>Odor threshold</b>	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	No data available	None known
pH (as aqueous solution)	No data available	None known
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known

<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Flash point</b>	No data available	None known
<b>Autoignition temperature</b>	No data available	None known
<b>Decomposition temperature</b>		None known
<b>Kinematic viscosity</b>	No data available	None known
<b>Dynamic viscosity</b>	No data available	None known
<b>Water solubility</b>	No data available	None known
<b>Solubility(ies)</b>	No data available	None known
<b>Partition coefficient</b>	No data available	None known
<b>Vapor pressure</b>	No data available	None known
<b>Relative density</b>	No data available	None known
<b>Bulk density</b>	No data available	
<b>Liquid Density</b>	No data available	
<b>Vapor density</b>	No data available	None known
<b>Particle characteristics</b>		
<b>Particle Size</b>	No information available	
<b>Particle Size Distribution</b>	No information available	

## 9.2. Other information

9.2.1. Information with regard to physical hazard classes  
Not applicable

9.2.2. Other safety characteristics  
No information available

## **SECTION 10: Stability and reactivity**

### 10.1. Reactivity

**Reactivity** No information available.

### 10.2. Chemical stability

**Stability** Stable under normal conditions.

#### **Explosion data**

**Sensitivity to mechanical impact** None.

**Sensitivity to static discharge** None.

### 10.3. Possibility of hazardous reactions

**Possibility of hazardous reactions** None under normal processing.

### 10.4. Conditions to avoid

**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.

### 10.5. Incompatible materials

**Incompatible materials** None known based on information supplied.

### 10.6. Hazardous decomposition products

**Hazardous decomposition products** None known based on information supplied.

**SECTION 11: Toxicological information****11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008****Information on likely routes of exposure****Product Information**

<b>Inhalation</b>	Specific test data for the substance or mixture is not available.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available.
<b>Skin contact</b>	Specific test data for the substance or mixture is not available.
<b>Ingestion</b>	Specific test data for the substance or mixture is not available.

**Symptoms related to the physical, chemical and toxicological characteristics**

**Symptoms** No information available.

**Numerical measures of toxicity**

**Acute toxicity** Based on available data, the classification criteria are not met

**Component Information**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium azide	= 27 mg/kg ( Rat )	= 20 mg/kg ( Rabbit )	0.054 - 0.52 mg/L ( Rat ) 4 h

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

<b>Skin corrosion/irritation</b>	No information available.
<b>Serious eye damage/eye irritation</b>	No information available.
<b>Respiratory or skin sensitization</b>	No information available.
<b>Germ cell mutagenicity</b>	No information available.
<b>Carcinogenicity</b>	Contains no ingredients above reportable quantities listed as a carcinogen.
<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<b>Aspiration hazard</b>	No information available.

**11.2. Information on other hazards****11.2.1. Endocrine disrupting properties**

**Endocrine disrupting properties** This product does not contain any known or suspected endocrine disruptors.

**11.2.2. Other information**

**Other adverse effects** No information available.

**SECTION 12: Ecological information****12.1. Toxicity****Ecotoxicity**

**Unknown aquatic toxicity** Contains 0 % of components with unknown hazards to the aquatic environment.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium azide	-	LC50: =0.8mg/L (96h, Oncorhynchus mykiss) LC50: =0.7mg/L (96h, Lepomis macrochirus) LC50: =5.46mg/L (96h, Pimephales promelas)	-	-

**12.2. Persistence and degradability**

**Persistence and degradability** No information available.

**12.3. Bioaccumulative potential**

**Bioaccumulation** No information available.

**12.4. Mobility in soil**

**Mobility in soil** No information available.

**12.5. Results of PBT and vPvB assessment****PBT and vPvB assessment**

Chemical name	PBT and vPvB assessment
Sodium azide	The substance is not PBT / vPvB PBT assessment does not apply

**12.6. Endocrine disrupting properties**

**Endocrine disrupting properties** This product does not contain any known or suspected endocrine disruptors.

**12.7. Other adverse effects**

No information available.

**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

<b>Waste from residues/unused products</b>	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
<b>Contaminated packaging</b>	Do not reuse empty containers.
<b>Waste codes / waste designations according to EWC / AVV</b>	According to the European Waste Catalog, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user based on the application for which the product was used.

**SECTION 14: Transport information****IATA**

<b>14.1 UN number or ID number</b>	Not regulated
<b>14.2 Extended Proper Shipping Name</b>	Not regulated
<b>14.3 Transport hazard class(es)</b>	Not regulated
<b>14.4 Packing group</b>	Not regulated
<b>14.5 Environmental hazards</b>	Not applicable
<b>14.6 Special precautions for user Special Provisions</b>	None

**IMDG**

<b>14.1 UN number or ID number</b>	Not regulated
<b>14.2</b>	
<b>14.3 Transport hazard class(es)</b>	Not regulated
<b>14.4 Packing group</b>	Not regulated
<b>14.5 Environmental hazards</b>	Not applicable
<b>14.6 Special precautions for user Special Provisions</b>	None
<b>14.7 Maritime transport in bulk according to IMO instruments</b>	No information available

**RID**

<b>14.1 UN number</b>	Not regulated
<b>14.2 Extended Proper Shipping Name</b>	Not regulated
<b>14.3 Transport hazard class(es)</b>	Not regulated
<b>14.4 Packing group</b>	Not regulated
<b>14.5 Environmental hazards</b>	Not applicable
<b>14.6 Special precautions for user Special Provisions</b>	None

**ADR**

<b>14.1 UN number or ID number</b>	Not regulated
<b>14.2 UN proper shipping name</b>	Not regulated
<b>14.3 Transport hazard class(es)</b>	Not regulated
<b>14.4 Packing group</b>	Not regulated
<b>14.5 Environmental hazards</b>	Not applicable
<b>14.6 Special precautions for user Special Provisions</b>	None

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****National regulations**

**Germany****Water hazard class (WGK)** non-hazardous to water (nwg)**European Union**

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

**Authorizations and/or restrictions on use:**

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV).

This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII).

**Persistent Organic Pollutants**

Not applicable

**Ozone-depleting substances (ODS) regulation (EC) 1005/2009**

Not applicable

**15.2. Chemical safety assessment****Chemical Safety Report**

No information available

**SECTION 16: Other information****Key or legend to abbreviations and acronyms used in the safety data sheet****Full text of H-Statements referred to under section 3**

EUH032 - Contact with acids liberates very toxic gas

H300 - Fatal if swallowed

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

**Legend**

SVHC: Substances of Very High Concern for Authorization:

**Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA

TWA (time-weighted average)

STEL

STEL (Short Term Exposure Limit)

Ceiling

Maximum limit value

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Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapor	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitization	Calculation method
Skin sensitization	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method

Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

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

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

**Issuing Date** 28-Jul-2015

**Revision Date** 27-Apr-2021

**Revision Note** Updated format.

**This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006**

**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**