

Issuing Date 19-Dec-2019

Revision Date 19-Dec-2019

Revision Number 0

<b>Section 1. Identification of the substance/mixture and of the company/undertaking</b>
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**1.1. Product identifier**

<b>Product Code(s)</b>	OCDUK6904485/707270/707135
<b>Product Name</b>	<b>Ortho BioVue® System (ABD Confirmation Cassette)/Ortho BioVue® System (ADK Cassette)</b>
<b>Synonyms</b>	<p>OCDUK6904485            Blood Grouping Reagents            Anti-A (Anti-ABO1) (Monoclonal)            Anti-B (Anti-ABO2) (Monoclonal)            Anti-D (Anti-RH1) (Monoclonal)            Ortho BioVue® System            (ABD Confirmation Cassette)</p> <p>OCDUK707270            Blood Grouping Reagents            Anti-A (Anti-ABO1) (Monoclonal)            Anti-B (Anti-ABO2) (Monoclonal)            Anti-D (Anti-RH1) (Monoclonal)            Anti-D (Anti-RH1) (Monoclonal)            Anti-K (Anti-K1) (Monoclonal)            Control            Ortho BioVue® System            (ADK Cassette)</p> <p>OCDUK707135            Blood Grouping Reagents            Anti-A (Anti-ABO1) (Monoclonal)            Anti-B (Anti-ABO2) (Monoclonal)            Anti-D (Anti-RH1) (Monoclonal)            Ortho BioVue® System            (ABD Confirmation Cassette)</p>

**Pure substance/mixture** Mixture

Contains 1-Imidazole.

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

<b>Recommended Use</b>	In vitro diagnostic
<b>Uses advised against</b>	No information available

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

<b>Importer</b>	<b>Supplier</b>
Ortho-Clinical Diagnostics 1500 Boulevard Sébastien Brant B.P. 30335 67411 Illkirch CEDEX, France	Ortho-Clinical Diagnostics, Inc. 1001 US Highway 202 Raritan, NJ 08869

**For further information, please contact**

<b>E-mail Address</b>	UK - ukhotline@orthoclinicaldiagnostics.com France - hotlinefrance@orthoclinicaldiagnostics.com Germany - ocdtechsupport-de@orthoclinicaldiagnostics.com Italy - italianhl@orthoclinicaldiagnostics.com Nordic - nordichotline@orthoclinicaldiagnostics.com
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Poland - service\_pl@pl.diasorin.com  
Portugal - port\_ocdhotline@orthoclinicaldiagnostics.com  
Irish Republic - ukhotline@orthoclinicaldiagnostics.com  
Spain - spanishhotline@orthoclinicaldiagnostics.com

**1.4. Emergency telephone number**

**Emergency Telephone  
Number**

**Transportation Emergencies:**

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

**US:**

(800) 421-3311

<b>Europe</b>	UK 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 Irish Republic 00 800 08372560 Spain 900 97 33 25
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**Section 2. Hazards identification**

**2.1. - Classification of the substance or mixture**

**REGULATION (EC) No 1272/2008**

Reproductive Toxicity	Category 1B
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**Physical Hazards**

None
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**2.2. Label Elements**



**Signal Word**

**Danger**

**Hazard Statements**

H360 - May damage fertility or the unborn child

**Precautionary Statements - EU (§28, 1272/2008)**

- P201 - Obtain special instructions before use
- P202 - Do not handle until all safety precautions have been read and understood
- P280 - Wear protective gloves, Eye Protection
- P308 + P313 - IF exposed or concerned: Get medical advice/ attention
- P405 - Store locked up
- P501 - Dispose of contents/ container to an approved waste disposal plant

### 2.3. 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.

## Section 3. Composition/information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Chemical Name	EC-No	CAS-No	Weight %	EU - GHS Substance Classification	REACH No.
Bovine Serum Albumin (BSA)	232-936-2	9048-46-8	1		No data available
1-Imidazole	206-019-2	288-32-4	0.43	Acute Tox. 4 (H302) Skin Corr. 1C (H314) Repr. 1B (H360D)	No data available
Hydrochloric Acid	231-595-7	7647-01-0	0.384	Skin Corr. 1A (H314) STOT SE 3 (H335) Press. Gas Acute Tox. 3 (H331)	No data available
Sodium azide	247-852-1	26628-22-8	0.097	Acute Tox. 2 (H300) (EUH032) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	No data available

For the full text of the H-Statements mentioned in this Section, see Section 16

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59).

## Section 4. First aid measures

### 4.1. Description of first-aid measures

<b>Eye Contact</b>	Rinse thoroughly with plenty of water, also under the eyelids. Get medical attention if irritation occurs.
<b>Skin Contact</b>	Wash skin with soap and water. Get medical attention if symptoms occur.
<b>Ingestion</b>	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.
<b>Inhalation</b>	Move to fresh air.

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

**Most Important Symptoms/Effects** No information available.

### 4.3. Indication of immediate medical attention and special treatment needed

**Notes to Physician** Treat symptomatically.

## Section 5. Fire-fighting measures

### 5.1. Extinguishing media

#### **Suitable Extinguishing Media**

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

#### **Extinguishing media which must not be used for safety reasons**

No information available.

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

##### **Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases**

None known.

#### **5.3. Advice for firefighters**

##### **Special protective equipment for fire-fighters**

As in any fire, wear self-contained breathing apparatus and full protective gear.

### **Section 6. Accidental release measures**

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

Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Use personal protective equipment. 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.

##### **Advice for emergency responders**

For personal protection see section 8.

#### **6.2. Environmental precautions**

Prevent further leakage or spillage if safe to do so.

#### **6.3. Methods and materials for containment and cleaning up**

Wipe up with absorbent material (e.g. cloth, fleece). 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.

#### **6.4. Reference to other sections**

Personal protection equipment (PPE) - Refer to Section 8. Disposal - Refer to Section 13.

### **Section 7. Handling and storage**

#### **7.1. Precautions for Safe Handling**

##### **Handling**

Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Remove and wash contaminated clothing before re-use.

##### **Hygiene Measures**

Handle in accordance with good industrial hygiene and safety practice. Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

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

Keep container tightly closed in a dry and well-ventilated place. Store according to label instructions. Store locked up.

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

##### **Exposure Scenario**

No information available.

#### **Risk Management Measures**

The information required is contained in this Safety Data Sheet

**Other Guidelines**

No information available.

**Section 8. Exposure controls/personal protection**

**8.1. Control parameters**

**Exposure Limits**

Chemical Name	EU	The United Kingdom	France	Spain	Germany
Hydrochloric Acid 7647-01-0	TWA 5 ppm TWA 8 mg/m <sup>3</sup> STEL 10 ppm STEL 15 mg/m <sup>3</sup>	STEL: 5 ppm STEL: 8 mg/m <sup>3</sup> TWA: 1 ppm TWA: 2 mg/m <sup>3</sup>	STEL: 5 ppm STEL: 7.6 mg/m <sup>3</sup>	STEL: 10 ppm STEL: 15 mg/m <sup>3</sup> TWA: 5 ppm TWA: 7.6 mg/m <sup>3</sup>	TWA: 2 ppm TWA: 3.0 mg/m <sup>3</sup> Ceiling / Peak: 4 ppm Ceiling / Peak: 6 mg/m <sup>3</sup>  TWA: 3 mg/m <sup>3</sup>
Sodium azide 26628-22-8	S* 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> Skin	TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup>	S* STEL: 0.3 mg/m <sup>3</sup> TWA: 0.1 mg/m <sup>3</sup>	TWA: 0.2 mg/m <sup>3</sup> Ceiling / Peak: 0.4 mg/m <sup>3</sup>
Component	Italy	Portugal	The Netherlands	Finland	Denmark
Hydrochloric Acid 7647-01-0 ( 0.384 )	TWA: 5 ppm TWA: 8 mg/m <sup>3</sup> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>	STEL: 10 ppm STEL: 15 mg/m <sup>3</sup> Ceiling: 2 ppm TWA: 5 ppm TWA: 8 mg/m <sup>3</sup>	STEL: 15 mg/m <sup>3</sup> TWA: 8 mg/m <sup>3</sup>	STEL: 5 ppm STEL: 7.6 mg/m <sup>3</sup>	Ceiling: 5 ppm Ceiling: 8 mg/m <sup>3</sup>
Sodium azide 26628-22-8 ( 0.097 )	TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup> Skin	STEL: 0.3 mg/m <sup>3</sup> Ceiling: 0.29 mg/m <sup>3</sup> Ceiling: 0.11 ppm TWA: 0.1 mg/m <sup>3</sup>	Skin 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> Skin	TWA: 0.1 mg/m <sup>3</sup> Skin
Chemical Name	Austria	Switzerland	Poland	Norway	Ireland
Hydrochloric Acid 7647-01-0	STEL 10 ppm STEL 15 mg/m <sup>3</sup> TWA: 5 ppm TWA: 8 mg/m <sup>3</sup>	STEL: 4 ppm STEL: 6 mg/m <sup>3</sup> TWA: 2 ppm TWA: 3 mg/m <sup>3</sup>	STEL: 10 mg/m <sup>3</sup> TWA: 5 mg/m <sup>3</sup>	Ceiling: 5 ppm Ceiling: 7 mg/m <sup>3</sup>	TWA: 8 mg/m <sup>3</sup> TWA: 5 ppm STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
Sodium azide 26628-22-8	Skin STEL 0.3 mg/m <sup>3</sup> TWA: 0.1 mg/m <sup>3</sup>	STEL: 0.4 mg/m <sup>3</sup> TWA: 0.2 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>	TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup> Skin

**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** No information available.

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

**8.2. Exposure controls**

**Engineering Measures** Showers.  
Eyewash stations.  
Ventilation systems.

**Personal protective equipment**

**Eye Protection** Safety glasses with side-shields.  
**Skin and Body Protection** Impervious clothing.  
**Hand Protection** Impervious gloves.  
**Respiratory Protection** When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

Environmental Exposure Controls No information available.

## Section 9. Physical and chemical properties

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

Physical State	Liquid.	Appearance	Clear.
Odor	None.		
<b>Property</b>	<b>Values</b>	<b>Remarks/ - Method</b>	
pH	6.9 - 7.1	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	
Vapor Pressure	No data available	None known	
Vapor Density	No data available	None known	
Relative Density	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	
Explosive Properties	No data available		
Oxidizing Properties	No data available		

### 9.2. Other information

VOC Content (%) No information available  
Flammability Limits in Air No data available

## Section 10. Stability and reactivity

### 10.1. Reactivity

Not reactive under normal conditions.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

None under normal processing.

### 10.4. 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

No information available.

### 10.6. Hazardous decomposition products

None under normal use.

## Section 11. Toxicological information

### 11.1. Information on toxicological effects

**Acute Toxicity**

**Product Information**

**Inhalation** No known effect based on information supplied.  
**Eye Contact** No known effect based on information supplied.  
**Skin Contact** No known effect based on information supplied.  
**Ingestion** No known effect based on information supplied.

**Component Information**

Chemical Name	LD50 Oral	LD50 Dermal	Inhalation
1-Imidazole	= 220 mg/kg ( Rat )		
Hydrochloric Acid	238 - 277 mg/kg ( Rat )	> 5010 mg/kg ( Rabbit )	= 1.68 mg/L ( Rat ) 1 h
Sodium azide	= 27 mg/kg ( Rat )	= 20 mg/kg ( Rabbit )	-

**Sensitization** No information available  
**Mutagenic Effects** No information available.  
**Carcinogenic Effects** Contains no ingredients above reportable quantities listed as a carcinogen.  
**Reproductive Toxicity** May damage fertility or the unborn child.  
**Developmental Toxicity** No information available.  
**STOT - single exposure** No information available.  
**STOT - repeated exposure** No information available.  
**Other Adverse Effects** No information available.  
**Aspiration Hazard** No information available.

**Section 12. Ecological information**

**12.1. Toxicity**

**Ecotoxicity Effects**

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)
1-Imidazole	EC50 72 h: = 130 mg/L (Desmodesmus subspicatus) EC50 96 h: = 82 mg/L (Desmodesmus subspicatus)		EC50 = 1200 mg/L 17 h EC50 = 231 mg/L 30 min	EC50 48 h: = 341.5 mg/L (Daphnia magna)
Sodium azide		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)		

**12.2. Persistence and degradability**

No information available.

**12.3. Bioaccumulative potential**

Chemical Name	Log Pow
1-Imidazole	-0.02

**12.4. Mobility in soil**

No information available.

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

No information available.

**12.6. Other adverse effects**

This product does not contain any known or suspected endocrine disruptors.

**Section 13. Disposal considerations**

**13.1. Waste treatment methods**

**Waste from Residues / Unused Products** Dispose of in accordance with local regulations.

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

**Section 14. Transport information**

**IMDG/IMO**

14.1. UN-Number	Not regulated.
14.2. Proper Shipping Name	Not regulated.
14.3. Hazard Class	Not regulated.
14.4. Packing Group	Not regulated.
Description	Not applicable.
14.5. Marine Pollutant	None.
14.6. Special Provisions	None.
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available.

**RID**

14.1. UN-Number	Not regulated.
14.2. Proper Shipping Name	Not regulated.
14.3. Hazard Class	Not regulated.
14.4. Packing Group	Not regulated.
Description	Not applicable.
14.5. Environmental hazard	None.
14.6. Special Provisions	None.

**ADR**

14.1. UN-Number	Not regulated.
14.2. Proper Shipping Name	Not regulated.
14.3. Hazard Class	None.
14.4. Packing Group	Not regulated.
14.5. Environmental hazard	None.
14.6. Special Provisions	None.

**IATA/ICAO**

14.1. UN-Number	Not regulated.
14.2. Proper Shipping Name	Not regulated.

14.3. Hazard Class	Not regulated.
14.4. Packing Group	Not regulated.
Description	Not applicable.
14.5. Environmental hazard	None.
14.6. Special Provisions	None.

## Section 15. Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### **Candidate List of Substances of Very High Concern for Authorization**

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59)

### 15.2. Chemical Safety Assessment

No information available

## Section 16. Other information

#### **Full text of H-Statements referred to under sections 2 and 3**

EUH032 - Contact with acids liberates very toxic gas

H300 - Fatal if swallowed

H302 - Harmful if swallowed

H314 - Causes severe skin burns and eye damage

H331 - Toxic if inhaled

H335 - May cause respiratory irritation

H360D - May damage the unborn child

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

#### **Key literature references and sources for data**

[www.ChemADVISOR.com/](http://www.ChemADVISOR.com/)

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Revision Note Initial Release.

This safety data sheet complies with the requirements of Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No. 1907/2006

#### 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