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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) 6842785

Product Name ORTHO CONFIDENCE WB Simulated Whole Blood Quality Control Kit

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**Importer**

Ortho-Clinical Diagnostics
1500 Boulevard Sébastien Brant
B.P. 30335
67411 Illkirch
CEDEX, France

Supplier

Ortho-Clinical Diagnostics, Inc.
1001 US Highway 202
Raritan, NJ 08869

and/or

Ortho-Clinical Diagnostics Australia Pty Ltd
Level 2, 8 Nexus
Court, Nexus
Corporate Park
Mulgrave, Victoria
3170

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
Australia/New Zealand - orthocareanz-support@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

Europe	UK and Irish Republic 0 800 895963 France 03 88 65 47 33
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	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 Australia +61 1800 032 359 New Zealand +64 0800 800 705
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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.

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 chloride 7647-14-5	0.42	No data available	231-598-3	[C]			

Classification according to Regulation (EC) No. 1272/2008 [CLP] - Notes

[C] - Components with occupational exposure limits and/or biological occupational exposure limits requiring monitoring

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_{mix}) 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 chloride	3000	10000	> 42		

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
7647-14-5					

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

Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician.
Ingestion	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

Symptoms	No information available.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.
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SECTION 5: Firefighting measures

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	No information available.
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5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters	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

Personal precautions 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. Ensure adequate ventilation.

For emergency responders 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 Take up mechanically, placing in appropriate containers for disposal.

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	Ireland	Italy	Italy REL	Latvia	Lithuania
Sodium chloride 7647-14-5	-	-	-	TWA: 5 mg/m ³	TWA: 5 mg/m ³

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 Wear safety glasses with side shields (or goggles).

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective clothing.

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

Physical state	Liquid
Appearance	Clear liquid
Color	Red
Odor	None.
Odor threshold	No information available

Property	Values	Remarks • Method
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
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
pH	No data available	None known
pH (as aqueous solution)	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	No data available	None known
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Vapor pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Vapor density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	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.

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

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion 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 chloride	= 3 g/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat) 1 h

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

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity 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.

Aspiration hazard 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

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium chloride	-	LC50: 5560 - 6080mg/L (96h, Lepomis)	-	EC50: =1000mg/L (48h, Daphnia magna)

		macrochirus) LC50: =12946mg/L (96h, Lepomis macrochirus) LC50: 6020 - 7070mg/L (96h, Pimephales promelas) LC50: =7050mg/L (96h, Pimephales promelas) LC50: 6420 - 6700mg/L (96h, Pimephales promelas) LC50: 4747 - 7824mg/L (96h, Oncorhynchus mykiss)		EC50: 340.7 - 469.2mg/L (48h, Daphnia magna)
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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 chloride	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

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

Waste codes / waste designations according to EWC / AVV 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 Not regulated
 14.1. UN number Not regulated
 14.2 UN proper shipping name Not regulated
 14.3. Transport hazard class(es) Not regulated
 14.4. Packing group Not regulated
 14.5 Environmental hazards Not applicable
 14.6 Special precautions for user
 Special Provisions None

IMDG Not regulated
 14.1. UN number Not regulated
 14.2 UN proper shipping name Not regulated
 14.3. Transport hazard class(es) Not regulated
 14.4. Packing group Not regulated
 14.5 Environmental hazards Not applicable
 14.6 Special precautions for user
 Special Provisions None
 14.7 Maritime transport in bulk according to IMO instruments No information available

RID Not regulated
 14.1. UN number Not regulated
 14.2 UN proper shipping name Not regulated
 14.3. Transport hazard class(es) Not regulated
 14.4. Packing group Not regulated
 14.5 Environmental hazards Not applicable
 14.6 Special precautions for user
 Special Provisions None

ADR Not regulated
 14.1. UN number Not regulated
 14.2 UN proper shipping name Not regulated
 14.3. Transport hazard class(es) Not regulated
 14.4. Packing group Not regulated
 14.5 Environmental hazards Not applicable
 14.6 Special precautions for user
 Special Provisions None

SECTION 15: Regulatory information

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

National regulations

France

Occupational Illnesses (R-463-3, France)

Chemical name	French RG number
Sodium chloride 7647-14-5	RG 78

Germany

Water hazard class (WGK) slightly hazardous to water (WGK 1)

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

Persistent Organic Pollutants

Not applicable

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

Not applicable

EU - Plant Protection Products (1107/2009/EC)

Chemical name	EU - Plant Protection Products (1107/2009/EC)
Sodium chloride - 7647-14-5	Plant protection agent

Biocidal Products Regulation (EU) No 528/2012 (BPR)

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Sodium chloride - 7647-14-5	1 - Human hygiene

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

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 * 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

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Revision Note Initial Release.

This safety data sheet complies with the requirements of: Annex to the Safety Data Sheet according to Regulation (EC) No 1907/2006 [REACH]

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