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Revision Number 0

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Code(s) OCDUS930800/930820/6902511CD

Product Name ORTHO HCV 3.0 ELISA Test System with Enhanced SAVe Conjugate

Pure substance/mixture Mixture

Contains PROCLIN 300

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 OCD ESC 24, Bld Sebastien Brant BP 30335 Illkirch Graffenstaden 67411 France	Supplier Ortho-Clinical Diagnostics, Inc. 1001 US Highway 202 Raritan, NJ 08869
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For further information, please contact

E-mail Address UK - uk hotline@its.jnj.com
 French - hotlinefrance@its.jnj.com
 German - ocdtechsupport-de@its.jnj.com
 Italian - italianhl@its.jnj.com
 Nordic - nordichotline@its.jnj.com
 Polish - polskahl@its.jnj.com
 Portuguese - Port_OCDhotline@its.jnj.com
 South Ireland - UKhotline@its.jnj.com
 Spanish - spanishhotline@its.jnj.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

Europe	UK 0800 895 963 French 03 88 65 47 33 German 0800 181 48 97 Italian 800 870 655 Nordic 00800 0837 2560 Polish 0800 331 13 58 Portuguese 800 83 31 43 South Ireland +33 (0) 3 88 65 47 63 Spanish 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

Skin Sensitization	Category 1
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Physical Hazards

None

2.2. Label Elements



Signal Word

Warning

Hazard Statements

H317 - May cause an allergic skin reaction

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

P280 - Wear protective gloves/ protective clothing
 P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
 P333 + P313 - If skin irritation or rash occurs: Get medical advice/ attention
 P363 - Wash contaminated clothing before reuse

2.3. Other information

Product contains animal-derived biologicals. May cause allergic reactions. 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.
Serum albumin	232-936-2	9048-46-8	2		No data available
PROCLIN 300	-	N/A	1	Skin Corr. 1B (H314) Skin Sens. 1 (H317) Acute Tox. 4 (H302) Acute Tox. 4 (H312) Acute Tox. 4 (H332) Aquatic Chronic 2 (H411)	No data available
Heat Inactivated Horse Serum	-	N/A	1		No data available

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

Note

The listing of the classification of Proclin 300 is attributed to the percentage of the mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one (3:1), CAS 55965-84-9, present in Proclin 300.

Section 4. First aid measures

4.1. Description of 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 plenty of water for at least 15 minutes. In the case of skin irritation or allergic reactions see a physician.
Ingestion	Rinse mouth. Do NOT induce vomiting. Drink plenty of water. Never give anything by mouth to an unconscious person. Get medical attention.
Inhalation	IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing Get medical attention

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

Most Important Symptoms/Effects May cause allergic skin reaction. Itching. Hives. Rashes.

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

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.

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.

Clean contaminated surface thoroughly. Clean with disinfectants.

6.4. Reference to other sections

See Section 12 for additional information.

Section 7. Handling and storage

7.1. 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.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Keep at temperatures between 2 °C and 8 °C. Do not freeze.

7.3. Specific end use(s)

Exposure Scenario

No information available.

Other Guidelines

No information available.

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

This product, as supplied, does not contain any hazardous materials with occupational exposure 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

Ensure adequate ventilation, especially in confined areas.

Personal protective equipment

Eye Protection

If splashes are likely to occur, wear: Safety glasses with side-shields.

Skin and Body Protection

Lightweight protective clothing.

Hand Protection

Protective gloves.

Respiratory Protection None required under normal usage.

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	Light yellow brown.
Odor	Odorless		

<u>Property</u>	<u>Values</u>	<u>Remarks/ - Method</u>
pH	7.0 - 7.4	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. Ignitions sources - heat, sparks and open flames.

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	Not an expected route of exposure. No known hazard by inhalation. Acute or repeated inhalation of aerosol or mist may cause a systemic allergic reaction.
Eye Contact	No known hazard by eye contact. May cause slight irritation.
Skin Contact	May cause sensitization by skin contact.
Ingestion	No hazard from product as supplied. May cause allergic reactions in susceptible individuals.
Sensitization	May cause sensitization by skin contact.
Mutagenic Effects	No information available.
Carcinogenic Effects	No information available.
Reproductive Toxicity	No information available.
Developmental Toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	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.

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential.

No information available.

12.4. Mobility in soil

Adsorbs on soil.

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

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.

IATA

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

International Inventories

TSCA Exempt

EINECS/ELINCS	Exempt
DSL/NDSL	Exempt
PICCS	Exempt
ENCS	Exempt
IECSC	Exempt
AICS	Exempt
KECL	Exempt

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

15.2. Chemical Safety Assessment

No information available

Section 16. Other information

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

H314 - Causes severe skin burns and eye damage

H317 - May cause an allergic skin reaction

H302 - Harmful if swallowed

H312 - Harmful in contact with skin

H332 - Harmful if inhaled

H411 - Toxic to aquatic life with long lasting effects

Key literature references and sources for data

www.ChemADVISOR.com/

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Revision Note Initial Release.

This safety data sheet complies with the requirements of Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No. 1907/2006

General Disclaimer

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End of Safety Data Sheet