

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

GHS product identifier

Product Name ORTHO ELISA Test System OPD Tablets

Other means of identification

Product Code(s) OCDUS930740/930750/933245/933275/6901968/6901969OP

UN-Number UN1673

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

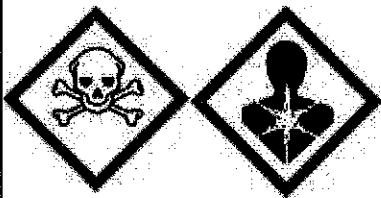
Classification

Acute Oral Toxicity	Category 3
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Acute Dermal Toxicity	Category 4
Acute Inhalation Toxicity - Dusts and Mists	Category 4
Serious Eye Damage/Eye Irritation	Category 2
Skin Sensitization	Category 1
Germ Cell Mutagenicity	Category 2
Carcinogenicity	Category 2

Label Elements

Emergency Overview

Signal Word	Danger
Hazard Statements	
<ul style="list-style-type: none"> • Toxic if swallowed • Harmful if inhaled • Harmful in contact with skin • Causes serious eye irritation • May cause an allergic skin reaction • Suspected of causing genetic defects • Suspected of causing cancer 	
	
Appearance White to off-white, Tablet.	Physical State Solid.
Odor No information available.	

Precautionary Statements

Prevention

- Avoid breathing dust/fume/gas/mist/vapors/spray.
- Use only outdoors or in a well-ventilated area
- Wash face, hands and any exposed skin thoroughly after handling.
- Do not eat, drink or smoke when using this product.
- Obtain special instructions before use.
- Do not handle until all safety precautions have been read and understood.
- Use personal protective equipment as required
- Contaminated work clothing should not be allowed out of the workplace
- Wear protective gloves/protective clothing/eye protection/face protection

General Advice

- If exposed or concerned: Get medical attention/advice

Eyes

- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- If eye irritation persists: Get medical advice/attention.

Skin

- IF ON SKIN: Wash with plenty of soap and water.
- Call a POISON CENTER or doctor/physician if you feel unwell.
- Wash contaminated clothing before reuse.

- If skin irritation or rash occurs: Get medical advice/attention.

Inhalation

- IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

Ingestion

- IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
- Rinse mouth.

Storage

- Store locked up.

Disposal

- Dispose of contents/container to an approved waste disposal plant.

Physical and Health Hazards Not Otherwise Classified

Not applicable.

Other Information

May cause an allergic skin reaction.

Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.

45% 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)
o-Phenylenediamine dihydrochloride	615-28-1	30-50	-	-
Non-hazardous Ingredients	N/A	45	-	-
Sodium hydrogensulfite	7631-90-5	1-5	-	-

4. FIRST AID MEASURES

Description of necessary 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 persists.
Skin Contact	Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. If skin irritation or rash occurs: Get medical advice/attention.
Inhalation	IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention.
Ingestion	Immediate medical attention is required. Clean mouth with water and afterwards drink plenty of water. Do NOT induce vomiting. Never give anything by mouth to an unconscious person.

Most important symptoms/effects, acute and delayed

Most Important Symptoms/Effects Difficulty in breathing. Coughing and/ or wheezing. May cause allergic skin reaction.

Drowsiness. Dizziness, weakness. Convulsions.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to Physician Treat symptomatically.

6. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Water spray. Carbon dioxide (CO₂). Dry chemical. Alcohol-resistant foam.

Unsuitable Extinguishing Media

None known based on information supplied.

Specific Hazards Arising from the Chemical

Thermal decomposition can lead to release of irritating and toxic gases and vapors: Carbon oxides, Nitrogen oxides (NO_x).

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.

8. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions

Ensure adequate ventilation Ensure trained personnel conduct clean up. Use personal protective equipment. Refer to Section 8. Avoid dust formation Avoid contact with skin, eyes and clothing.

Environmental Precautions

Environmental Precautions

Avoid release to the environment. Collect spillage. Dispose of contents/container to an approved waste disposal plant. Prevent further leakage or spillage if safe to do so. Do not allow material to contaminate ground water system. Prevent product from entering drains. See Section 12 for additional Ecological Information.

Methods and materials 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. Keep in suitable and closed containers for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Avoid dust formation. Avoid breathing dust.

Conditions for safe storage, including any incompatibilities

Storage

Keep container tightly closed in a dry and well-ventilated place. Keep at temperatures between 2 °C and 8 °C.

Incompatible Products Strong oxidizing agents.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

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. If splashes are likely to occur, wear: Tightly fitting safety goggles. Face-shield.

Skin and Body Protection Lightweight protective clothing. Long sleeved clothing. Impervious clothing. Chemical resistant gloves. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Respiratory Protection If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.

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	Solid.	Appearance	White to off-white, Tablet.
Odor	No information available.	Odor Threshold	No information available.

<u>Property</u>	<u>Values</u>	<u>Remarks/ - Method</u>
pH	4.8 - 5.2	None known
Melting Point/Range	258 °C / 496 °F	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
Relative Density		None known
Specific Gravity	No data available	None known
Water Solubility	Soluble in water.	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	None known based on information supplied.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Carbon oxides. Nitrogen oxides (NOx).

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information	
Inhalation	Harmful by inhalation.
Eye Contact	Causes serious eye irritation.
Skin Contact	Harmful in contact with skin. May cause sensitization by skin contact.
Ingestion	Toxic if swallowed. Effects to the nervous system (autonomic and parasympathomimetic), convulsions, and muscle weakness were demonstrated in animal studies.

Chemical Name	LD50 Oral	LD50 Dermal	Inhalation
Sodium hydrogensulfite	= 1310 mg/kg (Rat)	-	-

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Allergic skin reactions or irritation.
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Delayed and immediate effects and also chronic effects from short and long term exposure

Sensitization	May cause an allergic skin reaction.
Mutagenic Effects	In vitro tests have shown mutagenic effects.
Carcinogenicity	Contains a known or suspected carcinogen.

Chemical Name	ACGIH	IARC	NTP	OSHA
o-Phenylenediamine		Group 2B		X

dihydrochloride			
Sodium hydrogensulfite		Group 3	

ACGIH: (American Conference of Governmental Industrial Hygienists)
A3 - Animal Carcinogen

Reproductive Toxicity No information available
STOT - single exposure No information available.
STOT - repeated exposure No information available.
Target Organ Effects Eyes. Skin. Nervous system.
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 45% of the mixture consists of ingredient(s) of unknown toxicity.
LD50 Oral 109 mg/kg; Acute toxicity estimate
LD50 Dermal 1210 mg/kg; Acute toxicity estimate
Inhalation dust/mist 1.6 mg/L; Acute toxicity estimate
Acute Oral Toxicity 45% of the mixture consists of ingredient(s) of unknown acute oral toxicity
Acute Dermal Toxicity 45% of the mixture consists of ingredient(s) of unknown acute dermal toxicity
GHS-Acute Inhalation (Dust/Mist) Toxicity 45% of the mixture consists of ingredient(s) of unknown acute inhalation (dust/mist) toxicity
GHS-Acute Inhalation (Vapor) Toxicity 45% of the mixture consists of ingredient(s) of unknown acute inhalation (vapor) toxicity
GHS-Acute Inhalation (Gas) Toxicity 45% of the mixture consists of ingredient(s) of unknown acute inhalation (gas) toxicity

12. ECOLOGICAL INFORMATION

Ecotoxicity

The environmental impact of this product has not been fully investigated.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Sodium hydrogensulfite 7631-90-5				EC50 48 h: = 119 mg/L (Daphnia magna)

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.

14. TRANSPORT INFORMATION

DOT

UN-Number UN1673
Proper shipping name Phenylenediamines
Hazard Class 6.1

Packing Group III
Description UN1673, Phenylenediamines, 6.1, III
Emergency Response Guide Number 153

TDG

UN-Number UN1673
Proper Shipping Name Phenylenediamines
Hazard Class 6.1
Packing Group III
Description UN1673, Phenylenediamines, 6.1, III, Marine Pollutant

MEX

UN-Number UN1673
Proper Shipping Name Phenylenediamines
Hazard Class 6.1
Packing Group III
Description UN1673, Phenylenediamines, 6.1, III

IATA

UN-Number UN1673
Proper Shipping Name Phenylenediamines
Hazard Class 6.1
Packing Group III
ERG Code 6L
Special Provisions A113
Description UN1673, Phenylenediamines, 6.1, III

IMDG/IMO

UN-Number UN1673
Proper Shipping Name Phenylenediamines
Hazard Class 6.1
Packing Group III
EmS No. F-A, S-A
Special Provisions 279
Marine Pollutant Product is a marine pollutant according to the criteria set by IMDG/IMO
Description UN1673, Phenylenediamines, 6.1, III, Marine Pollutant

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 contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372:

Chemical Name	CAS-No	Weight %	SARA 313 - Threshold Values %

o-Phenylenediamine dihydrochloride	615-28-1	30-50	1.0
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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 contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42):

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Sodium hydrogensulfite	5000 lb			X

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 hydrogensulfite	5000 lb		RQ 5000 lb final RQ RQ 2270 kg final RQ

U.S. State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals:

Chemical Name	CAS-No	California Prop. 65
o-Phenylenediamine dihydrochloride	615-28-1	Carcinogen

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
o-Phenylenediamine dihydrochloride	X				
Sodium hydrogensulfite	X	X	X		

16. OTHER INFORMATION

NFPA	Health Hazard 2	Flammability 0	Instability 0	Physical and Chemical Hazards -
HMIS	Health Hazard 2*	Flammability 0	Physical Hazard 0	Personal Protection X

*Indicates a chronic health hazard.

Prepared By Product Stewardship
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Latham, NY 12110
1-800-572-6501

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Revision Note Initial Release.

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 Other

