Ortho Clinical Diagnostics

SAFETY DATA SHEET

Issuing Date 01-Jun-2015 **Revision Date** 01-Jun-2015 **Revision Number** 0

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

GHS product identifier

Product Name **VITROS Chemistry Products TDM Performance Verifier III**

Other means of identification

Product Code(s) **OCDUS8182172**

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended Use Diagnostic agent

Uses advised against No information available

Supplier's details

Supplier Address
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626-5101

Customer service telephone:(800) 421-3311

Emergency telephone number

Emergency Telephone Number

Regional Emergency Telephone Number:
French 03 88 65 47 33
Spanish 900 97 33 25

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

2. HAZARDS IDENTIFICATION

Classification

Skin Sensitization	Category 1

GHS Label elements, including precautionary statements

Emergency Overview

Signal Word **Warning**

Hazard Statements
• May cause an allergic skin reaction



Appearance Transparent, Gold **Physical State** Frozen, Liquid. **Odor** Odorless

Precautionary Statements

Prevention

- Avoid breathing dust/fume/gas/mist/vapors/spray.
- Contaminated work clothing should not be allowed out of the workplace.
- Wear protective gloves.
- Wash face, hands and any exposed skin thoroughly after handling.

General Advice

- Specific treatment (see supplemental instructions on the administration of antidotes on this label)

Skin

- IF ON SKIN: Wash with plenty of soap and water.
- If skin irritation or rash occurs: Get medical advice/attention.
- Wash contaminated clothing before reuse.
- Take off contaminated clothing and wash before reuse.

Storage

- None

Disposal

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

Hazard Not Otherwise Classified (HNOC)

Not applicable

Other information

May cause an allergic skin reaction. 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.

< 1% of the mixture consists of ingredient(s) of unknown toxicity.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %
Bovine Serum Albumin (BSA)	9048-46-8	7.05882
PROCLIN 300	N/A	0.05098

The listing of Proclin 300 as a hazardous component is attributed to the percent of a 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.

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. Get medical attention if irritation occurs.

Skin Contact Wash off immediately with soap and plenty of water for at least 15 minutes while removing all contaminated clothing and shoes. In the case of skin irritation or allergic reactions see a physician.

Inhalation IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention. IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing.

Ingestion Rinse mouth. Do NOT induce vomiting. Drink plenty of water. Never give anything by mouth to an unconscious person. Get medical attention.

Most important symptoms/effects, acute and delayed

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

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

Notes to Physician Treat symptomatically.

5. FIRE-FIGHTING MEASURES

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

Unsuitable Extinguishing Media None. No information available.

Specific Hazards Arising from the Chemical
No information available.

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.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions Ensure adequate ventilation. Wear suitable gloves and eye/face protection. 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.

Environmental Precautions

Environmental Precautions Do not allow material to contaminate ground water system.

Methods and materials for containment and cleaning up

Methods for Containment Wipe up with absorbent material (e.g. cloth, fleece). Pick up and transfer to properly labeled containers.

Methods for Cleaning Up Clean contaminated surface thoroughly. Clean with disinfectants.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Wear personal protective equipment. Refer to Section 8. Wash thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Storage Store according to label instructions. Keep containers tightly closed in a dry, cool and well-ventilated place. Store at -18°C / 0°F.

Incompatible Products None known.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

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.
Skin and Body Protection Long sleeved clothing. Impervious gloves.
Respiratory Protection None required under normal usage.

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 Frozen, Liquid.
Odor Odorless.
Appearance Transparent, Gold.
Odor Threshold No information available.

Property	Values	Remarks/ - Method
pH	7.5	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
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
Specific Gravity	~1	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

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

Heat.

Incompatible materials

None known.

Hazardous decomposition products

None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation	May cause irritation.
Eye Contact	May cause slight irritation.
Skin Contact	May cause sensitization by skin contact.
Ingestion	Not expected to be toxic following ingestion.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain, or flushing. Allergic skin reactions or irritation.

Delayed and immediate effects and also chronic effects from short and long term exposure

Sensitization	May cause an allergic skin reaction.
Mutagenic Effects	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.
Target Organ Effects	Skin.
Aspiration Hazard	No information available.

Numerical measures of toxicity - Product

Acute Toxicity < 1% of the mixture consists of ingredient(s) of unknown toxicity.

The following values are calculated based on chapter 3.1 of the GHS document:

LD50 Oral > 5000 mg/kg; Acute toxicity estimate; (ATE)

LD50 Dermal > 5000 mg/kg; Acute toxicity estimate

12. ECOLOGICAL INFORMATION

Ecotoxicity

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)
Acetaminophen 103-90-2		LC50 96 h: = 814 mg/L flow-through (Pimephales promelas)	EC50 = 1000 mg/L 30 min EC50 = 1050 mg/L 15 min EC50 = 1120 mg/L 5 min	EC50 48 h: 6.1 - 14 mg/L (Daphnia magna)
Caffeine 58-08-2		LC50 96 h: = 151 mg/L flow-through (Pimephales promelas)		EC50 4 h: = 182.12 mg/L (Daphnia species)
Carbamazepine 298-46-4		LC50 96 h: = 43 mg/L (Brachydanio rerio)		EC50 48 h: = 0.414 mg/L Static (Daphnia magna) EC50 24 h: = 92 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 This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

Contaminated Packaging Do not re-use empty containers.

14. TRANSPORT INFORMATION

DOT Not regulated

TDG Not regulated

IATA Not regulated

IMDG/IMO Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA Exempt

DSL Exempt

NDSL Exempt

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

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 %
Phenytoin	57-41-0	0.00279	0.1

SARA 311/312 Hazard Categories

Acute Health Hazard	Yes
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

Clean Water Act

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

U.S. State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals:

Chemical Name	CAS-No	California Prop. 65
Phenytoin	57-41-0	Carcinogen Developmental
Carbamazepine	298-46-4	Developmental
Primidone	125-33-7	Carcinogen

U.S. State Right-to-Know Regulations

This product does not contain any substances above threshold limits that are regulated by state right-to-know.

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

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

Prepared By Product Stewardship
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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