Ortho Clinical Diagnostics

SAFETY DATA SHEET

Issuing Date 05-Jun-2018 **Revision Date** 27-Dec-2018 **Revision Number** 1

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

GHS product identifier

Product Name **VITROS Chemistry Products HbA1c Calibrator Kit 31**

Other means of identification

Product Code(s) **OCDUS6842906**

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
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

Serious Eye Damage/Eye Irritation	Category 1
Respiratory Sensitization	Category 1
Skin Sensitization	Category 1

Specific Target Organ Toxicity (Repeated Exposure)	Category 2

Label Elements

Emergency Overview

Signal Word **Danger**

Hazard Statements
• Causes serious eye damage
• May cause allergy or asthma symptoms or breathing difficulties if inhaled
• May cause an allergic skin reaction
• May cause damage to organs through prolonged or repeated exposure



Appearance Red brown. **Physical State** Solid. **Odor** Odorless.

Precautionary Statements

Prevention
• In case of inadequate ventilation wear respiratory protection.
• Contaminated work clothing should not be allowed out of the workplace
• Do not breathe dust/fume/gas/mist/vapors/spray.
• Wear protective gloves/protective clothing/eye protection/face protection

General Advice
• Get medical attention/advice if you feel unwell

Eyes
• IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
• Immediately call a POISON CENTER or doctor/physician.

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.

Inhalation
• IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing
• If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

Storage
• None

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. May cause allergic respiratory reaction. Causes mild skin irritation.

15.03% 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)
Sucrose	57-50-1	40-70	-	-
Tetradecyltrimethylammonium bromide (TTAB)	1119-97-7	5-10	-	-
Lauryl polyethylene glycol ether	9002-92-0	1-5	-	-
3(2H)-Isothiazolone, 2-methyl-, hydrochloride	26172-54-3	0.1-1	-	-

4. FIRST AID MEASURES

Description of necessary first-aid measures

General Advice Immediate medical attention is required.

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Do not rub affected area. Call a physician or Poison Control Center immediately.

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: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

Ingestion Do NOT induce vomiting. Clean mouth with water and afterwards drink plenty of water. Never give anything by mouth to an unconscious person. Call a physician or Poison Control Center immediately.

Protection of First-aiders Use personal protective equipment. Avoid contact with skin, eyes and clothing.

Most important symptoms/effects, acute and delayed

Most Important Symptoms/Effects Serious eye irritation or damage. 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 No information available

Specific Hazards Arising from the Chemical May cause sensitization by inhalation and skin contact.

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

Environmental Precautions

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

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Ensure adequate ventilation Avoid contact with skin, eyes and clothing. Avoid dust formation Wear personal protective equipment. In case of insufficient ventilation, wear suitable respiratory equipment Handle product only in closed system or provide appropriate exhaust ventilation at machinery.

Conditions for safe storage, including any incompatibilities

Storage Keep containers tightly closed in a dry, cool and well-ventilated place Keep in properly labeled containers

Incompatible Products Incompatible with strong acids and bases. Incompatible with oxidizing agents

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Sucrose 57-50-1	TWA: 10 mg/m³	TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction (vacated) TWA: 15 mg/m³ total dust (vacated) TWA: 5 mg/m³ respirable fraction	TWA: 10 mg/m³ total dust TWA: 5 mg/m³ respirable dust

Chemical Name	Alberta	British Columbia	Ontario	Quebec
Sucrose	TWA: 10 mg/m³	TWA: 10 mg/m³ TWA: 3 mg/m³	TWA: 10 mg/m³	TWA: 10 mg/m³

Appropriate engineering controls

Engineering Measures Showers
Eyewash stations
Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/Face Protection Tightly fitting safety goggles.
Skin and Body Protection Impervious clothing. Impervious gloves. Boots. Chemical resistant apron.
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 When using, do not eat, drink or smoke. Remove and wash contaminated clothing before re-use. Provide regular cleaning of equipment, work area and clothing. Keep away from food, drink and animal feeding stuffs. Contaminated work clothing should not be allowed out of the workplace. For environmental protection, remove and wash all contaminated protective equipment before re-use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	Solid.	**Appearance**	Red brown.
Odor	Odorless.	**Odor Threshold**	Not applicable.

Property	Values	Remarks/ - Method
pH	Not applicable	None known
Melting Point/Range	No data available	None known
Boiling Point/Boiling Range	No information available	None known
Flash Point	Not applicable.	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	Not applicable	None known
Specific Gravity	No data available	None known
Water Solubility	Completely soluble	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	Not applicable	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 No data available.

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 Do not freeze Dust formation Exposure to air or moisture over prolonged periods

Incompatible materials Incompatible with strong acids and bases. Incompatible with oxidizing agents

Hazardous decomposition products Thermal decomposition can lead to release of irritating gases and vapors.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation May cause irritation of respiratory tract
Eye Contact Causes serious eye damage.
Skin Contact Causes mild skin irritation.
Ingestion Ingestion may cause irritation to mucous membranes

Chemical Name	LD50 Oral	LD50 Dermal	Inhalation
Sucrose	29700 mg/kg (Rat)	-	-
Tetradecyltrimethylammonium bromide (TTAB)	= 1000 mg/kg (Rat)	-	-
Lauryl polyethylene glycol ether	= 1 g/kg (Rat)	-	-

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Burning Allergic skin reactions or irritation. 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.

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

Sensitization May cause sensitization by skin contact. May cause sensitization by inhalation.
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 Causes damage to organs through prolonged or repeated exposure if swallowed
Target Organ Effects Eyes. Skin. Respiratory 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 15.03% of the mixture consists of ingredient(s) of unknown toxicity.
LD50 Oral 6080 mg/kg; Acute toxicity estimate mg/kg mg/L

12. ECOLOGICAL INFORMATION

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

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 Not regulated

TDG Not regulated

MEX Not regulated

IATA Not regulated

IMDG/IMO Not regulated.

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 does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

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 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 does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

"X" designates that the ingredients are listed on the state right to know list.

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
Sucrose	-	X	X	-	X

16. OTHER INFORMATION

NFPA	**Health Hazard** 3	**Flammability** 0	**Instability** 0	**Physical and Chemical Hazards** -
HMIS	**Health Hazard** 3	**Flammability** 0	**Physical Hazard** 0	**Personal Protection** X

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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

Ortho PRODUCT Category VITROS Chemistry Systems
Ortho SUB-CATEGORY Class Calibrator