

**MicroGEM US Inc.**705D – Dale Avenue
Charlottesville, VA 22903Email: techsupportdx@microgembio.com
Web: www.microgembio.com/covid-19

Safety Data Sheet

SECTION 1: PRODUCT IDENTIFICATION and COMPANY IDENTIFICATION

Product Name	MicroGEM Sal6830 SARS-CoV-2 Saliva Test (USA) Sal6830 SARS-CoV-2 Saliva Testing Kit (CAN)
Generic Name	N/A
Synonyms	N/A
Product Codes	SCF0001, SCF0030, SCF0001-CAN, SCF0030-CAN
Test Components	Cap (Pouch A), Saliva Cup (Pouch B), Test Cartridge (Pouch C), Detection System for SARS-CoV-2
Product Description	The SARS-CoV-2 Saliva Test is an automated real-time <i>RT-qPCR</i> diagnostic test for qualitative detection of nucleic acid from the SARS-CoV-2 virus.
REACH Registration number	A registration number is not available for this substance as the substance or its use is exempt from REACH Regulation (EC) No 1907/2006, the annual tonnage does not require a registration.
CAS #	N/A – mixture
Date of Revision	August 2022
Company Support	Email: techsupportdx@microgembio.com
Manufacturer Details in USA	MicroGEM US Inc, 705D Dale Avenue, Charlottesville, VA 22903 Emergency telephone: +1-800-222-1222 (National Poison Centre)

SECTION 2: HAZARD IDENTIFICATION**Potential Health Effects:**

Australia: NOHSC 2011 National Code of Practice: This product is not considered hazardous according to safe work Australia

New Zealand: This product is considered a Manufactured Article in New Zealand.

USA: OSHA Regulatory Status: This material is not considered hazardous under the OSHA standard or WHMIS.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Contains	CAS #	Weight %
Water and Nonhazardous ingredients	Proprietary	To 100%

SECTION 4: FIRST AID MEASURES

Inhalation	Not considered a route of exposure.
Ingestion	Not considered a route of exposure.
Skin	Not considered a route of exposure.
Eyes	Not considered a route of exposure.
Most important symptoms and effects, both acute and delayed	None known.

SECTION 5: FIRE FIGHTING MEASURES

Fire	Flash point: Not flammable
Extinguishing Media	Use appropriate media for the surrounding fire
Explosion	Not considered an explosion hazard
Special Precautions	None known

In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full face piece operated in the pressure demand or other positive pressure mode.

SECTION 6: ACCIDENTAL RELEASE MEASURES


Wear appropriate personal protective equipment as specified in Section 8.

Collect liquid in an appropriate container or absorb with an inert material (e. g., vermiculite, dry sand, earth), and place in a chemical waste container. Wash contaminated area with plenty of water. Dispose as per Section 13

SECTION 7: HANDLING AND STORAGE

Read label before use. Store only in the original container.

SECTION 8: EXPOSURE CONTROL/ PERSONAL PROTECTION

OSHA Permissible Exposure Limits (PELs)	N/A
American Conference Limits of Governmental Industrial Hygienists (ACGIH)	N/A
Threshold Limit Values (TLVs)	N/A
Exposure Limits - Other	N/A
Engineering Controls	N/A
Skin and body Protection	 <p>Good practice to wear protective gloves.</p>
Eye Contact	N/A
Inhalation	N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Hard shell cartridge containing Liquid
Odor	Odorless
Odor Threshold	N/A
pH	N/A
Boiling Point	N/A
Melting Point	N/A
Freezing Point	N/A
Flash Point	N/A
Flammability	N/A
Upper and Lower Explosive Limits	N/A
Vapor Pressure	N/A
Vapor Density	N/A
Specific Gravity	N/A
Water Solubility	Complete
Partition Coefficient:	N/A
Auto-ignition Temperature	N/A
Decomposition Temperature	N/A
Kinematic Viscosity	N/A
Particle Characteristics	N/A

SECTION 10: STABILITY AND REACTIVITY

Chemical Stability	This product is stable in closed containers at room temperature.
Hazardous Decomposition Products	None known.
Incompatibilities	None known.
Conditions to Avoid	None known.

SECTION 11: TOXICOLOGICAL INFORMATION

Acute Effects:

Swallowed	N/A
Dermal	N/A
Inhalation	N/A
Eye	N/A
Skin	N/A

Chronic Effects:

Carcinogenicity	N/A
Reproductive Toxicity	N/A
Germ Cell Mutagenicity	N/A
Aspiration	N/A
STOT/SE	N/A
STOT/RE	N/A

SECTION 12: ECOLOGICAL INFORMATION

New Zealand:

HSNO Classes: This product is not hazardous to the environment.

Environmental Fate: No data available

SECTION 13: DISPOSAL CONSIDERATIONS

As a waste, this material in its raw form IS NOT considered a HAZARDOUS WASTE under RCRA (29 CFR 261).

Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

Used cartridges to be disposed according to Local Regulations.

SECTION 14: TRANSPORT INFORMATION

This product is NOT classified as a Dangerous Good for transport

Proper Shipping Name:	Not regulated by DOT, TDG, IATA, IMDG
DOT Hazard Class:	N/A
UN Number:	N/A
Packing Group:	N/A
CERCLA Reportable Quantity (RQ):	N/A

Releases exceeding the reportable quantity (RQ) must be reported to the National Response Center (800) 424-8802. This data provided for information only. The description shown may not apply to all shipping situations. Consult 49 CFR, or appropriate regulations to properly classify your shipment for transportation.

SECTION 15: REGULATORY INFORMATION

New Zealand:

This substance is NOT classified hazardous according to the EPA Hazardous Substances (Classification) Notice 2017

TSCA Chemical Inventory: All of the chemicals in this product are listed on the TSCA Inventory.

TSCA Sec 4 Chemical Test Rule: None of the chemicals in this product are under a Chemical Test Rule.

TSCA Sec 8(d): None of the chemicals in this product are on the Health and Safety Reporting List.

TSCA Sec 12(b) Notices of Export: None of the chemicals in this product are on this list.

TSCA Significant New Use Rule (SNUR): None of the chemicals in this product are on this list.

SARA Sec 302 (EHS) TPQ: None of the chemicals in this product have a TPQ.

SARA Sec 302 (EHS) RQ: None of the chemicals in this product have a RQ.

SARA Sec 311/312: Acute – NO; Chronic – NO; Fire – NO; Release of Pressure – NO; Reactivity – NO

SARA 313 List: No materials in this product are reportable under Section 313 Title III and 40 CFR Part 372.

CERCLA Hazardous Substances and corresponding RQs: N/A

RCRA: None of the chemicals in this product are on this list.

Clean Air Act: Hazardous Air Pollutants? NO Class 1 Ozone Depletors? NO Class 2 Ozone Depletors? NO

Clean Water Act: Hazardous Substance? NO Priority Pollutant? NO Toxic Pollutant? NO

Chemical Weapons Convention: None of the chemicals in this product are on this list.

Drug Enforcement Agency (DEA) CDTA: None of the chemicals in this product are on this list.

OSHA: None of the chemicals in this product are considered Highly Hazardous by OSHA.

State Right-to-Know Lists: None of the materials in this product are found on the Right-to-Know lists of California, Florida, New Jersey, Pennsylvania, Massachusetts, or Minnesota.

SECTION 16: OTHER INFORMATION

Abbreviations and acronyms used:

ACGIH	American Conference of Governmental Industrial Hygienists	NA	not applicable, not available
ANSI	American National Standards Institute	NIOSH	National Institute for Occupational Safety and Health
atm	atmosphere (pressure unit)	ND	not determined
BOD	biological oxygen demand	NFPA	National Fire Prevention Association
CAS	Chemical Abstracts Service	NTP	National Toxicology Program
CC	closed cup	OC	open cup
CDTA	Chemical Drug and Trafficking Act	OSHA	Occupational Safety and Health Administration
COC	Cleveland Open Cup	Part	partition
COD	chemical oxygen demand	PEL	permissible exposure limits
coeff.	coefficient	ppb	parts per billion
CFR	Code of Federal Regulations	PPE	personal protective equipment
CPR	cardio-pulmonary resuscitation	ppm	parts per million
DEA	Drug Enforcement Agency	psi	pounds per square inch
DOT	Department of Transportation	RCRA	Resource Conservation and Recovery Act
FDA	Food and Drug Administration	RQ	Reportable quantity
IARC	Internat'l Agency for Research on Cancer	RTK	Right to Know
IDLH	immediate danger to life and health	SARA	Superfund Amendments and Reauthorization Act
kg	kilogram	STEL	short-term exposure limit
L	liter	TCC	Tagliabue Closed Cup
LC50	median lethal concentration	TPQ	threshold planning quantity
LD50	median lethal dose	TQ	threshold quantity
LEL	lower explosive limit	TSCA	Toxic Substances Control Act
mg	milligram	TWA	time-weighted average
mL	milliliter	WHMIS	Workplace Hazardous Materials Information System

NZ References:

1. EPA Hazardous Substances (Safety Data Sheets) Notice 2017
2. Workplace Exposure Standards and Biological Exposure Indices Nov 2017 edition.
3. Assigning a hazardous substance to a HSNO Approval (Aug 2013).
4. Transport of Dangerous goods on land NZS 5433:2012
5. HSW (Hazardous Substances) Regulations 2017

This document was prepared in accordance with 29 CFR 1910.1200 and ANSI Z400.1-2004.

DISCLAIMER: Although the information and recommendations set forth herein (hereinafter "Information") are presented in good faith and believed to be correct as of the date hereof, the Company makes no representations as to the completeness or accuracy thereof. Information is supplied upon the condition that the persons receiving this MSDS will make their own determination as to its suitability for their intended purposes prior to use. Since the product is within the exclusive control of the user, it is the user's obligation to determine the conditions of safe use of this product. Such conditions should comply with all Federal Regulations concerning the Product. It must be recognized that the physical and chemical properties of any product may not be fully understood and that new, possibly hazardous products may arise from reactions between chemicals. The information given in this data sheet is based on our present knowledge and shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER NATURE ARE MADE HEREUNDER WITH RESPECT TO INFORMATION OR THE PRODUCT TO WHICH INFORMATION REFERS. **THIS IS THE LAST PAGE OF SDS.**