

SECTION 1: IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

1.1 Product Name: REDx™ Controls Formulated with Methanol Based Transport Medium

1.2 Product codes: Refer to Appendix 1

1.3. Manufacturer details: Microbix Biosystems Inc.

Address: 265 Watline Avenue, Mississauga, ON, Canada, L4Z 1P3 (Head Office) Telephone: 905-361-8910 Fax : 905-361-8911

1.4 Emergency telephone number: CANUTEC at 1-888-CAN-UTEC (226-8832) CHEMTREC, International: 703-527-3887.

1.5 Recommended use: For In Vitro Diagnostic (IVD) use.

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture GHS Classification in accordance with: Canada Hazardous Products Regulations (HPR) (SOR/2015-17) USA Hazard Communication Standard 2012 OSHA (29 CFR 1910.1200)

Flammable liquids (Category 3), Acute toxicity, Oral (Category 3), Acute toxicity, Inhalation (Category 3), Acute toxicity, Dermal (Category 3), Specific target organ toxicity - single exposure (Category 1), Eyes.

2.2 GHS Label elements, including precautionary statements

Pictogram



Signal word

Danger

Hazard statement(s)

H226	Flammable liquid and vapour.
H301+H311+H331	Toxic if swallowed, in contact with skin or if inhaled.
H370	Causes damage to organs (Eyes).

Precautionary statement(s)

P210	,	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.
P233		Keep container tightly closed.
P260		Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P264		Wash skin thoroughly after handling.
P270 P280		Do not eat, drink or smoke when using this product.
F20U		Wear protective gloves/ protective clothing/ eye protection/ face protection.

ERG Code

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P303 + P361 + P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

P363 - Wash contaminated clothing before reuse.

P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

Fire: In case of fire: Use CO₂, dry chemical, or foam for extinction.



Precautionary Statements – Storage: P403 + P233 - Store in a well-ventilated place. Keep container tightly closed Precautionary Statements – Disposal: P501 - Dispose of contents/container in accordance with local/regional/national/international regulation.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS – contains inactivated bacterial and/or viral particles. These components are not considered to be hazardous to healthy human.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Mixtures

Chemical	CAS-Registry #	Wt (%)
Methanol	67-56-1	30-50%
Water	7732-18-5	50-70%
Inactivated bacterial and/or viral particles	N/A	N/A

Note: All product codes listed in appendix 1, with the exception of RED-99-M1, RED-99-M3, contain inactivated bacterial and/or viral particles. Although, these components are inactivated and are not considered to be hazardous to healthy humans at their given concentrations.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General advice: Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled: Remove individual to fresh air and seek medical attention.

In case of eye contact: Irrigate immediately with copious amounts of water for at least 15 minutes. Seek medical attention. In case of skin contact: Remove contaminated clothing and shoes. Immediately wash affected area with copious amounts of water. Seek medical attention.

If swallowed: Wash out mouth with water provided the person is conscious. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Seek medical attention.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media Dry powder; Dry sand Unsuitable extinguishing media Do NOT use water jet.

- 5.2 Special hazards arising from the substance or mixture Carbon oxides, Sulphur oxides
- **5.3 Advice for firefighters** Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information Use water spray to cool unopened containers.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment, and emergency procedures

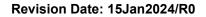
Use suitable protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Ventilate the area of leak or spill. Remove all sources of ignition. Isolate hazard area.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Contain spillage, clean any spillage by immediately by absorbing with an inert material and dispose of all specimens, samples and materials used in testing as though they contain biohazardous agent.





SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

These products contain inactivated bacterial and/or viral particles.

WARNING:

The reagent has been inactivated and should contain no infectious material; however, handle as capable of transmitting infectious agents Biosafety Risk Group 1/Biosafety Level 1. Appropriate safety procedures should be employed when handling this product according to applicable biosafety guidelines.

Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources.

Do not ingest or inhale. Wash thoroughly after handling. Avoid contact with eyes, skin, and clothing.

7.2 Conditions for safe storage, including any incompatibilities

Store this product at 2-8°C.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters:

Canada

Component name	British Columbia OEL	Quebec OEL	Ontario TWA
Methanol	TWA: 200 ppm	TWA: 200 ppm	TWA: 200 ppm
67-56-1	STEL: 250 ppm	TWA: 262 mg/m ³	STEL: 250 ppm
	Skin	STEL: 250 ppm	Skin
		STEL: 328 mg/m ³	
		Skin	

United States of America

Component name	ACGIH TLV	OSHA PEL	NIOSH IDLH*
Methanol	STEL: 250 ppm	TWA: 200 ppm	IDLH: 6000 ppm
67-56-1	TWA: 200 ppm	TWA: 260 mg/m ³	TWA: 200 ppm
	S*	(vacated) TWA: 200 ppm	TWA: 260 mg/m ³
		(vacated) TWA: 260 mg/m ³	STEL: 250 ppm
		(vacated) STEL: 250 ppm	STEL: 325 mg/m ³
		(vacated) STEL: 325 mg/m ³	
		(vacated) S*	

*NIOSH IDLH Immediately Dangerous to Life or Health

Mexico

Component	Exposure Limits
Methanol	Mexico: TWA 200 ppm
67-56-1 (35-55)	Mexico: STEL 250 ppm

8.2 Exposure controls

Appropriate engineering controls: Supply ventilation to keep vapour levels below threshold limit value. Respiratory protection: Where engineering controls are not adequate, wear appropriate NIOSH vapor respirator.

Use an approved/certified respirator or equivalent.

Eye protection: Eyewear with side shields or goggles.

Skin protection: Nitrile rubber gloves

Other protective clothing or equipment: Wear suitable protective clothing.

Work hygienic practices: There are no known hazards associated with this material when used as recommended. Follow good industry hygiene practices.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties (based on methanol component)
Physical state: Liquid
Color: Colorless

pH: 5.5



Appearance: Clear, colourless liquid. Odor: No data available. Odor threshold No information available

FLAMMABILITY:

Flash point: 26 °C / 78 °F (closed cup) LEL = 13.6% UEL = 36% (based on methanol component)

Specific gravity: 0.92 Autoignition temperature 460 °C / 860 °F Solubility in water: Complete Freezing point: N/A Viscosity: N/A **VOC content:** N/A Vapor density: 1.1 Vapor pressure mm/Hg: 127 Boiling point: 64.5°C

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity No data available

10.2 STABILITY: Stable used under normal conditions. CONDITIONS TO AVOID (STABILITY): Avoid heating, high temperatures, incompatible materials, ignition sources, oxidizers.

10.3 INCOMPATIBILITY (MATERIAL TO AVOID): Incompatible with strong oxidizers acids and metals.

- 10.4 HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: May form carbon dioxide, carbon monoxide and formaldehyde when heated to decomposition.
- 10.5 HAZARDOUS POLYMERIZATION: Will not occur CONDITIONS TO AVOID (POLYMERIZATION): Not Available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effect (For Methanol component):

INHALATION:	LC50 Rat: 64,000 ppm/4H	
ORAL:	LD50 Rat: 5628 mg/kg	
	LD50 Mouse: 7300 mg/kg	
DERMAL	LD50 Rabbit: 15800 mg/kg	

Target Organ Effects Central nervous system, Eyes, Gastrointestinal tract (GI), Respiratory system, Skin. Unknown Acute Toxicity 50% of the mixture consists of ingredient(s) of unknown toxicity

Methanol may be fatal or cause blindness if swallowed; effects due to ingestion may include Nausea, Dizziness, Gastrointestinal disturbance, Weakness, Confusion., Drowsiness, Unconsciousness. To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

SECTION 12: ECOLOGICAL INFORMATION:

12.1 Ecotoxicity 50% of the mixture consists of components(s) of unknown hazards to the aquatic environment

12.2 Persistence and degradability No data available

12.3. Bioaccumulative potential:

Component name	Partition coefficient			
Methanol	-0.77			
12.4 Mobility in soil: No data available				

12.4. MODILITY IN SOII: NO data available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 WASTE DISPOSAL METHOD:

Always dispose of in accordance with local, state and federal regulations. Dispose of all specimens, samples and materials



used in testing as though they contain biohazardous agents. **Contaminated packaging:** Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

For methanol-based products: Excepted packaging is authorized for limited quantities that would pose a very low hazard if released in an accident.

For methanol mixtures not excepted packaging:

TDG

UN/ID no UN1992 Proper Shipping Name FLAMMABLE LIQUID, N.O.S. Hazard Class 3 Packing group III Description UN1992, FLAMMABLE LIQUID, N.O.S. (Methanol), 3, III

ΙΑΤΑ

UN/ID no UN1992 Proper Shipping Name Flammable liquid, toxic, N.O.S. Hazard Class 3 Subsidiary hazard class 6.1 Packing group III Description UN1992, Flammable liquid, toxic, N.O.S (Methanol), 3 (6.1), III Environmental Hazard Not applicable Special Provisions None ERG Code 3P

DOT

UN/ID no UN1992 Proper Shipping Name FLAMMABLE LIQUIDS, N.O.S. Hazard Class 3 Packing group III Description UN1992, FLAMMABLE LIQUIDS, N.O.S. (Methanol), 3, III Emergency Response Guide Number 128

IMDG UN/ID no UN1992 Proper Shipping Name FLAMMABLE LIQUID, N.O.S. Hazard Class 3 Packing group III EmS No. F-E, S-E Description UN1992, FLAMMABLE LIQUID, N.O.S. (Methanol), 3, III, (26°C C.C.)

SECTION 15: REGULATORY INFORMATION

For Methanol: CAS 67-56-1 – 30-50%

Canada: This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the CPR.

U.S. FEDERAL REGULATIONS TSCA (TOXIC SUBSTANCE CONTROL ACT): All ingredients listed on TSCA inventory SARA 313

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.

SARA 311/312: Fire hazard

SARA 311/312: Chronic Health Hazard

SARA 313 – Threshold Values 1.0% - Toxic pollutant reporting list

CWA (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.

Hazardous Substances Reportable Quantity (RQ): 5000 lb/2270 kg

California Proposition 65: Developmental.

SECTION 16: OTHER INFORMATION

Prepared By: Occupational Health and Safety Representative **Revision Date:** 15 January 2024

DISCLAIMER:

Microbix Biosystems Inc. provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgement in determining its appropriateness for a particular purpose. It may not be valid for this material if it is used in combination with any other materials. Microbix Biosystems Inc. makes no representations or warranties either express or implied, including without limitation any warranties of merchantability, fitness for a particular purpose with respect to the information set forth herein or the product to which the information refers. Accordingly, Microbix Biosystems Inc. will not be responsible for damages resulting from use or reliance upon this information.

SAFETY DATA SHEET

Appendix 1

REDx™ Controls Formulated with Methanol-Based Transport Medium

REDx™ SARS-CoV-2 Positive Control	RED-19-01
REDx™ Chlamydia trachomatis Positive Control	RED-12-M1
REDx™ Chlamydia trachomatis and Neisseria gonorrhea Positive Control	RED-12-M2
REDx™ <i>Neisseria gonorrhoeae</i> Positive Control	RED-17-M1
REDx™ HPV 16 Positive Control	RED-62-16
REDx™ HPV 18 Positive Control	RED-62-18
REDx™ HPV 31 Positive Control	RED-62-31
REDx™ HPV 33 Positive Control	RED-62-33
REDx™ HPV 39 Positive Control	RED-62-39
REDx™ HPV 45 Positive Control	RED-62-45
REDx™ HPV 51 Positive Control	RED-62-51
REDx™ HPV 52 Positive Control	RED-62-52
REDx™ HPV 66 Positive Control	RED-62-66
REDx™ hr-HPV Negative Control	RED-62-67
REDx™ HPV 16/18/45 Positive Control	RED-62-M1
REDX™ HPV 31/33/66 Positive Control	RED-62-M2
REDx™ HPV 39/51/52 Positive Control	RED-62-M3
REDx™ <i>Mycoplasma genitalium</i> Positive Control	RED-63-01
REDx™ SARS-CoV-2 Negative Control	RED-99-M3
REDx™ Sexually Transmitted Infections (STI) Negative Control	RED-99-M1

This product list will be updated with the addition of new products. List updated on 15012024