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SECTION 1: IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

1.1 Product name: **REDx™ Human Papillomavirus (HPV) Positive Control, REDx™ Human papillomavirus (HPV) Negative Control**

1.2 Synonym:

1.3 Product codes: RED-62-16, RED-62-18, RED-62-45, RED-99-M1

1.4 Supplier details: Microbix Biosystems Inc.

Address: 265 Watline Avenue, Mississauga, ON, Canada, L4Z 1P3 (Head Office)

Telephone: 905-361-8910 Fax: 905-361-8911

1.6 Emergency telephone number: +1-800-424-9300 for assistance (CHEMTREC)

International: 703-527-3887

1.6 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 Hazardous Products Regulations (HPR) (SOR/2015-17)

Flammable liquids (Category 2), 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)

Highly flammable liquid and vapour.

Toxic if swallowed, in contact with skin or if inhaled.

Causes damage to organs (Eyes).

Precautionary statement(s)

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

Keep container tightly closed.

Ground and bond container and receiving equipment.

Take action to prevent static discharges.

Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.

Wash skin thoroughly after handling.

Do not eat, drink or smoke when using this product.

Use only in a well-ventilated area.

Wear protective gloves/ protective clothing/ eye protection/ face protection.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - contains inactivated human cells with integrated HPV DNA and/or inactivated human cells. These components are not considered to be hazardous to health.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Mixtures

Chemical	CAS-Registry #	Wt (%)
Methanol	67-56-1	30-60%
Water	7732-18-5	40-70%
Inactivated human cells containing HPV DNA	N/A	N/A
and/or inactivated human cells		

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.

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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 ued in testing as though they contain biohazardous agent.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

The product contains inactivated human cells with integrated HPV DNA and/or human cells.

WARNING:

Handle controls as capable of transmitting infectious agents Biosafety Risk Group 1/Biosafety Level 1.

REDx HPV Positive Control is manufactured from human epithelial cells containing HPV DNA and other inactivated human cells that are grown in tissue culture and preserved in a buffered solution.

Appropriate safety procedures should be employed when handling this product according to applicable biosafety guidelines. 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: Methanol CAS-No. 67-56-1 Value TWA Control parameters: 200 ppm - 262 mg/m3

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. Be sure to use an approved/certified respirator or equivalent.

Eye protection: Goggles **Skin protection:** 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

FLAMMABILITY: Flash point: 72 °F, 22 °C (closed cup)

Flammable limits: LEL = 6.7, UEL = 36 (based on methanol component)

Flammable liquid and vapour

Lower flammability point: N/A

Appearance: Clear, colourless liquid. **Odor:** No data available.

Specific gravity: 0.92 Solubility in water: Complete Freezing point: N/A Viscosity: N/A Color: Colorless
Physical state: Liquid
VOC content: N/A
Vapor density: 1.1

Vapor pressure mm/Hg: 127 pH 5.5 Boiling point: 64.5°C

Auto-ignition temperature: 385°C

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No data available

10.1 STABILITY: Stable used under normal conditions.

CONDITIONS TO AVOID (STABILITY): Avoid heating, high temperatures, incompatible materials, ignition sources, oxidizers

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- 10.2 INCOMPATIBILITY (MATERIAL TO AVOID): Incompatible with strong oxidizers and acids.
- **10.3 HAZARDOUS DECOMPOSITION OR BY-PRODUCTS:** May form carbon dioxide, carbon monoxide and formaldehyde when heated to decomposition.
- 10.4 HAZARDOUS POLYMERIZATION: Will not occur

CONDITIONS TO AVOID (POLYMERIZATION): Not Available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

For Methanol:

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

DERMAL LD50 Rabbit: 15800 mg/kg

Methyl alcohol 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 Toxicity No data available

12.2 Persistence and degradability 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: DOT (US)

UN number: 1230 Class: 3 Packing group: II **Proper shipping name:** MethanolSOLUTION

IATA

UN number: 1230 Class: 3 (6.1) Packing group: II **Proper shipping name:** MethanolSOLUTION

SECTION 15: REGULATORY INFORMATION

For Methanol:

U.S. FEDERAL REGULATIONS

TSCA (TOXIC SUBSTANCE CONTROL ACT): All ingredients listed on TSCA inventory

SARA 311 Status: Immediate, fire hazard

SARA 311: Methanol is listed on the 313 Toxic pollutant reporting list.

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory: Yes

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s). A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

State regulations WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

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US - California Hazardous Substances (Director's): Listed substance

Methanol (CAS 67-56-1) Listed.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Methanol (CAS 67-56-1) Listed.

US - California Proposition 65 - CRT: Listed date/Developmental toxin **Methanol (CAS 67-56-1)** Listed: March 16, 2012 Developmental toxin.

US - New Jersev RTK - Substances: Listed substance

Methanol (CAS 67-56-1) Listed.

US. Massachusetts RTK - Substance List

Methanol (CAS 67-56-1) Listed.

US. New Jersey Worker and Community Right-to-Know Act

Methanol (CAS 67-56-1) 500 lbs

US. Pennsylvania RTK - Hazardous Substances

Methanol (CAS 67-56-1) Listed.

Mexico regulations This safety data sheet was prepared in accordance with the Official Mexican Standard (NOM-018-

STPS-2000).

SECTION 16: OTHER INFORMATION

Prepared By: Occupational Health and Safety Representative

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DISCLAIMER:

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