



DIAGNOSTIC AUTOMATION, INC.

21250 Califa Street, Suite 102 and 116, Woodland Hills, CA 91367

Tel: (818) 591-3030 Fax: (818) 591-8383

onestep@rapidtest.com

technicalsupport@rapidtest.com

www.rapidtest.com

Material Safety Data Sheet

Mitochondria

Manufacturer: Cortez Diagnostics Inc.
23961 Craftsman Rd. Suite D/E/F,
Calabasas, CA 91302 USA

Phone Number: (818) 591-3030

Product Name: Mitochondria

Catalog No. 1420-1

Composition / information on components

PREPARATION

Chemical nature: (composition with the main components and dangerous components)

Components contributing to the hazard:

TMB substrate/chromogen

| Chemical | Concentration | Units | CAS | EC Hazard symbol | R&S phrases |
|--------------------|---------------|-------|-----------|------------------|--------------------------|
| Dimethyl Sulfoxide | ≤ 1.0% | ml/ml | 67-68-5 | Not applicable | R 36/37/38 S 26,36,23 |
| Hydrogen Peroxide | ≤ 0.03% | ml/ml | 7722-84-1 | Not applicable | R 36/38 S 36 |

Stop Solution

| Chemical | Concentration | Units | CAS | EC Hazard symbol | R&S phrases |
|---------------|---------------|-------|-----------|------------------|-----------------------------|
| Sulfuric Acid | 5% | ml/ml | 7664-93-9 | Xi Irritant | R 36/38 S (1/2),26,36,23 |

Wash Buffer

| Chemical | Concentration | Units | CAS | EC Hazard symbol | R&S phrases |
|--------------|---------------|-------|-----------|--------------------|--------------------------|
| Hydrochloric | 0.24% | ml/ml | 7647-01-0 | Not applicable | R 34/37 S (1/2),26,45 |
| Trizma Base | 0.03% | g/ml | 77-86-1 | Not applicable | R 36/37/38 S 26,36 |
| Tween 80 | 4..3% | g/ml | 9005-65-6 | Category 3 Harmful | R 40 S 36 |

This preparation also contains Blue Food dye and Proclin as preservative.

Components presenting a hazard a danger: (dangerous products with concentrations under the hazard threshold)

High Positive Control

| Chemical | Concentration and Units |
|--------------|-------------------------|
| Sodium Azide | < 0.1% g/ml |

This preparation also contains Penicillin/Streptomycin and Mitochondria positive human serum.

Low Positive control

| Chemical | Concentration and Units |
|--------------|-------------------------|
| Sodium Azide | < 0.1% g/ml |

This preparation also contains Penicillin/Streptomycin and Mitochondria positive human serum.

Calibrator

| Chemical | Concentration and Units |
|--------------|-------------------------|
| Sodium Azide | < 0.1% g/ml |

This preparation also contains Penicillin/Streptomycin and Mitochondria positive human serum.

Negative Control

| Chemical | Concentration and Units |
|--------------|-------------------------|
| Sodium Azide | < 0.1% g/ml |

This preparation also contains Penicillin/Streptomycin and Mitochondria negative human serum.

Conjugate

This preparation contains Antihuman IgG,A,M conjugated to horse radish peroxidase, a conjugate stabilizer, and Proclin, Gentamycin sulfate and Bromonitrodioxane as preservatives.

Serum Diluent

| Chemical | Concentration and Units |
|-----------------------------|-------------------------|
| Sodium Phosphate, Monobasic | 0.02% g/ml |
| Sodium Phosphate, Dibasic | 0.02% g/ml |
| Tween 20 | 0.05% g/ml |

This preparation also contains BSA, Casein Hydrolysate, Enzymatic, Yellow food dye and Proclin as preservative.

Intended use: In vitro diagnostic for professional use.

Hazard Identification

MOST IMPORTANT HAZARDS:

The human serum components used in the preparation of the Controls and Calibrator in this kit have been tested by an FDA approved method for the presence of antibodies to human immunodeficiency virus 1 & 2 (HIV 1&2), hepatitis C (HCV) as well as hepatitis B surface antigen and found negative. Because no test method can offer complete assurance that HIV, HCV, hepatitis B virus, or other infectious agents are absent, specimens and human-based reagents should be handled as if capable of transmitting infectious agents.

LABEL PRECAUTIONARY STATEMENTS

Stop Solution

Xi Irritant

FOR SULFURIC ACID IN STOP SOLUTION PREPARATION: **DANGER!** CORROSIVE LIQUID AND MIST CAUSE SEVERE BURN TO ALL BODY TISSUE. MAY BE FATAL IF SWALLOWED OR CONTACTED WITH SKIN. HARMFUL IF INHALED. AFFECTS TEETH. CANCER HAZARD. STRONG INORGANIC ACID MISTS CONTAINING SULPHURIC ACID CAN CAUSE CANCER.

RISK OF CANCER DEPENDS ON DURATION AND LEVEL OF EXPOSURE. WEAR SUITABLE CLOTHING. IN CASE OF ACCIDENT OR IF YOU FEEL UNWELL, SEEK MEDICAL ADVICE IMMEDIATELY (SHOW THE LABEL WHERE POSSIBLE).

Wash Buffer

Harmful

FOR TWEEN 80 IN WASH BUFFER PREPARATION: HARMFUL. POSSIBLE RISK OF IRREVERSIBLE EFFECTS. WEAR SUITABLE PROTECTIVE CLOTHING. AVOID INHALATION, AVOID CONTACT WITH EYES, SKIN, AND CLOTHING. AVOID PROLONGED OR REPEATED EXPOSURE. IF SWALLOWED, WASH OUT MOUTH WITH WATER PROVIDED PERSON IS CONSCIOUS. CALL A PHYSICIAN. IF INHALED, REMOVE TO FRESH AIR. IF NOT BREATHING GIVE ARTIFICIAL RESPIRATION. IF BREATHING IS DIFFICULT, GIVE OXYGEN. IN CASE OF CONTACT, IMMEDIATELY WASH SKIN WITH SOAP AND COPIOUS AMOUNTS OF WATER. IN CASE OF CONTACT, IMMEDIATELY FLUSH EYES WITH COPIOUS AMOUNTS OF WATER FOR AT LEAST 15 MINUTES.

Adverse human health effects:

The following general hazard warnings apply to all the kit components

Potential Routes of Exposure:

Target organs: Skin Contact, eye contact, accidental ingestion, inhalation

Eye:

Excessive contact may cause eye irritation, redness, pain, burns

Sulfuric Acid: Corrosive. Effects should be less severe than from exposure to higher concentrations of sulphuric acid. Symptoms may include blurred vision, redness, pain, and burns to eye tissue.

Skin:

Direct or repeated contact may cause skin irritation. May be absorbed through the skin causing systemic effects (see effects for inhalation and ingestion). Dermatitis

Sulfuric Acid: Corrosive. Effects should be less severe than from exposure to higher concentrations of sulfuric acid. Symptoms may include redness, pain, and burns to the skin. Circulatory collapse with clammy skin, weak and rapid pulse, shallow respirations, and scanty urine may follow ingestion or skin contact.

Inhalation:

Do not breathe vapor.

Sulfuric Acid: Corrosive. Effects should be less severe than from exposure to higher concentrations of sulfuric acid. Symptoms may include irritation of the nose and throat, labored breathing, as well as lung edema, damage to the mucous membranes and upper respiratory tract.

Accidental ingestion:

General –Abdominal pain. Shortness of breath. Unconsciousness. Vomiting. Sweating. Drowsiness.

Sulfuric Acid: Corrosive. Effects should be less severe than from exposure to higher concentrations of sulphuric acid. Symptoms may include severe burns of the mouth, throat, and stomach. Circulatory

collapse with clammy skin, weak and rapid pulse, shallow respirations, and scanty urine may follow ingestion or skin contact. Circulatory shock is often the immediate cause of death. May cause sore throat, vomiting, diarrhea.

Chronic Toxicity

Prolonged or repeated contact may cause allergic dermatitis (redness, irritation, rash), may cause sensitization.

Sulfuric Acid: Long term exposure to mist or vapors may cause damage to teeth. Chronic exposure to mists containing sulphuric acid is a cancer hazard.

Reproductive and Developmental Toxicity:

None identified.

Carcinogenicity:

None identified for DMSO. Carcinogenicity applies to “strong inorganic acid mists containing sulfuric acid” but not to sulfuric acid or sulfuric acid solutions. Tween 80 is or contains a component that has been reported to be possibly carcinogenic based on its IARC, ACGIH, NTP OR EPA Classification

Medical Conditions Aggravated by Exposure:

DMSO: Eye Disorders, Skin disorders, Liver or Kidney disorders. Topical application enhances dermal absorption of many other chemicals, including drugs/allergens of moderate molecular weight.

Sulfuric Acid: Pre-existing skin disorders, eye problems, respiratory function may be more Susceptible to the effects of the substance.

Environmental effects:

See section 12 – Ecological Information

EC classification of the preparation:

TMB Substrate solution containing DMSO and Sulfuric acid are classified as irritants. As only a minimal amount of the preparation is provided with the TMB substrate and Stop Solution, container and packaging are not marked with the irritant symbol. Wash Buffer containing Tween 80 is classified as harmful. Warnings are provided in the package insert with regards to the use of this product and it is recommended that protective clothing be worn.

First-aid measures

The following general first aid measures apply to all components of the kit.

Inhalation:

Immediately move to fresh air and notify medical personnel. If not breathing give artificial respiration. If breathing difficult, give oxygen.

Skin contact:

Immediately wash thoroughly with soap and water for 15 minutes and notify medical personnel. Remove and wash contaminated clothing and shoes.

Eye contact:

Immediately flush eyes thoroughly with water for at least 15 minutes and notify medical personnel.

Ingestion:

If swallowed, wash out mouth with water and notify medical personnel. Remove and wash contaminated clothing and shoes.

Fire-fighting measures

The following general measures apply to all components of the kit.

Extinguishing media:

Use dry chemical foam or carbon dioxide. Water may not be effective.

Specific hazards:

For DMSO vapors may flow along surfaces to distant ignition sources and flash back. Closed containers exposed to heat may explode.

For sulphuric acid contact with most metals causes formation of flammable and explosive hydrogen gas.

Specific methods of fire-fighting:

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.

Structural fire-fighter's protective clothing is ineffective for fires involving sulphuric acid. Stay away from sealed containers.

Accidental release measures

Personal precautions:

Ventilate area of leak or spill. Wear appropriate personal protective equipment as specified in Section 8. Isolate hazard area. Keep unnecessary and unprotected personnel from entering.

Methods of cleaning up:

Contain liquid when possible. Use non sparking tools and equipment.

Absorb with an inert material (e.g., vermiculite, dry sand, earth), and place in a chemical waste container. Do not use combustible materials, such as saw dust.

Ventilate area and wash spill site after material pickup is complete.

Environmental precautions:

Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulation. Do not flush to sewers, storm drains, surface waters, and soil.

Handling and storage

Avoid contact with skin, eyes or clothing. Use adequate ventilation or minimize exposures to mists or aerosols. Wash thoroughly after handling. DO NOT permit contact with acids and other incompatible substances. Store at 2-8°C

Exposure control / Personal protection

Occupational Exposure Limits:

There are no established exposure limits for this product. However, the following exposure limits exist for the following hazardous ingredients:

| Ingredients: | OSHA PEL | ACGIH TLV | Other |
|-----------------|---------------------|---------------------|-------------------------------------|
| DMSO: | Not established | Not established | |
| Sulfuric Acid: | 1 mg/m ³ | 1 mg/m ³ | 3 mg/m ³ (STEL) Tween 80 |
| Not established | Not established | | |

Personal Protective Equipment:

Eye and Face Protection:

Wear safety glasses with side shield, or full face shield if eye contact is likely. The choice of protection should be based on the job activity and potential for exposure to eyes and face.

Respiratory protection:

When handling bulk quantities or for long durations where aerosolization of material is likely, wear a NIOSH – approved air purifying respirator.

Skin and body protection:

Wear gloves, lab coat, or other protective over-garment if skin contact is likely. The choice of skin protection should be based on the job activity and potential for exposure to the skin.

Hygiene measures:

Wash hands immediately after handling materials (especially before eating, drinking or smoking). Decontaminate or discard protective equipment after each use.

Remove personal protective equipment when leaving work area.

Physical and chemical properties

Not Applicable

Stability and reactivity

The kit should only be used as instructed in the package insert. See pack insert for further information of kit stability.

Toxicological information

Toxicological information is supplied for DMSO, Sulfuric Acid, and Tween 80 only. Other components of the preparation are not supplied at levels or quantities currently thought to have toxicological effects. Dimethyl sulphoxide (DMSO) is present at < 1 % in the TMB Substrate/Chromogen. Rtecs # pv6210000

Sulfuric Acid is present at 5 % in the Stop Solution. Tween 80 is present in 4.8% in Wash Buffer

Inhalation:

DMSO: No data

Sulfuric Acid: LD50 = 510 mg/m³/2H (rat) Tween 80:

Skin (Irritancy and Acute Toxicity):

DMSO: caused mild irritation to rabbit skin at 10 and 500 mg/24 hours.

Skn LD50 = 40 g/kg (rat). Skn LD50 = 50 g/kg (mouse). Ipr LD50 = 8200 mg/kg (rat). Scu LD50 = 12 gm/kg (rat). Scu LD50 = 14 gm/kg (mouse). Ipr LD50 = 2500 mg/kg (mouse) Sulfuric Acid: No info.

Tween 80: Ipr LD50 = 6804 mg/kg (rat). Ipr LD50 = 7600 mg/kg (mouse)

Eye (Irritancy and Acute Toxicity):

DMSO: caused mild irritation to rabbit eye at 100 and 500 mg for 24 hours. Sulfuric Acid: Standard Draize, eye, rabbit, 250 µg (severe)

Tween 80: caused mild irritation to rabbit eye at 150 mg.

Ingestion:

DMSO: LD50 = 14500 mg/kg (rat). LD50 = 7920 mg/kg (mouse). LD50 = >10gm/kg (dog).

LD50 = 12 gm/kg (chicken). LD50 = 21400 mg/kg (mam). Sulfuric Acid: LD50 = 2140 mg/kg (rat)

Tween 80: LD50 = 34500 ul/kg (rat). LD50 = 25 gm/kg (mouse). LD50 = 25 gm/kg (mam).

Sensitisation:

DMSO: No data

Sulfuric Acid: No data

Tween 80: No data

Chronic toxicity or long term toxicity:

DMSO: target organs: eyes, skin to the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Sulfuric Acid: Long term exposure to mist or vapors may cause damage to teeth.

Chronic exposure to mists containing sulphuric acid is a cancer hazard.

Tween 80: Target organ data: Behavioral (altered sleep time), cardiac (other changes)

This product is or contains a component that has been reported to be possibly carcinogenic based on its IARC, ACGIH, NTP or EPA classification. The chemical, physical, and toxicological properties have not been thoroughly investigated.

Specific effects:

Carcinogenicity

DMSO: None identified

Sulfuric Acid: None identified

Tween 80: This product is or contains a component that has been reported to be possibly carcinogenic based on its IARC, ACGIH, NTP or EPA classification.

Mutagenicity

DMSO: None identified

Sulfuric Acid: None identified

Tween 80: None identified

Reproduction toxicity

DMSO: None identified

Sulfuric Acid: None identified

Tween 80: None identified

Ecological information

DMSO: Does not biodegrade in soil, may leach into groundwater, may evaporate some. May evaporate in water. Not expected to significantly bioaccumulate. In air may be moderately degrade reaction with photochemically produced hydroxyl radicals. Environmental toxicity not known.

Sulfuric Acid: May leach into ground water. In air removed to moderate extent by wet deposition. Removed to moderate extent by dry deposition. Environmental toxicity- LD50 Flounder 100 to 330 ng/l/48 hr aerated water/ Conditions of bioassay not specified. LD50 Shrimp 80-90 mg/l/48 hr aerated water / Conditions of bioassay not specified. LD50 prawn 42.5 ppm/48 hr salt water / conditions of bioassay not specified. May be toxic to aquatic life.

Disposal considerations

Dispose of materials in this kit according to Federal, State and Local Requirements.

Transport information

Land transport ARD / RID:

| | |
|-------------------------|-------------------------------------|
| - ARD / RID class: | Not regulated |
| - Danger code: | Not regulated |
| - UN number: | Not regulated |
| - Hazard label: | Not regulated |
| - Description of goods: | <i>In vitro</i> diagnostic test kit |

Inland waterways ADN / ADNR: Not regulated

Sea IMDG: Not regulated

Air CAO / IATA: Not regulated

Regulatory information

Labeling according to EU guidelines:

Code letter and hazard designation:

TMB substrate/chromogen

- Risk phrases R:

R36

Irritating to eyes

R38

Irritating to skin.

- Safety phrases S:

S26

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S36

Wear suitable protective clothing.

S23

Do not breathe vapor.

Stop Solution

- Risk phrases R:

R36

Irritating to eyes

R38

Irritating to skin.

- Safety phrases S:

S1/2

Keep locked up and out of the reach of children

S26

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S36

Wear suitable protective clothing

S23

Do not breathe vapor.

Wash Buffer

- Risk phrases R:

R36

Irritating to eyes

R40

Possible risk of irreversible effects

- Safety phrases S:

S26

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S36

Wear suitable protective clothing.

S23

Do not breathe vapor.

Substance(S) responsible for major health hazards: DMSO, CAS # 67-68-5. Sulfuric Acid, CAS # 7664-93-9. Tween 80, CAS # 9005-65-6.

Other information

Recommended use:

This product is an in vitro diagnostic testing kit and should only be used according to its package insert instructions.

Others:

The above information is based on data available to Diagnostic Automation Inc. USA and is believed to be correct. Since the information may be applied under conditions beyond the control of Diagnostic Automation Inc. USA and with which the company may be unfamiliar, Diagnostic Automation Inc. USA does not assume any responsibility for the results of its use and all persons receiving it shall make their own determination of the effects, properties, and protections, which pertain to their particular conditions.

No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the material, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material.

| | |
|---------------------|------------------------|
| Date Adopted | 2016-05-13 |
| REF 1420-1 | DA-Mitochondria |



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21250 Califa Street, Suite 102 and 116, Woodland Hills, CA 91367

Tel: (818) 591-3030 Fax: (818) 591-8383

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