SAFETY DATA SHEET

| SAFETY DATA SHEET | |
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| Section 1: Identification | |
| Product Identifier | QwikCheck™ MaleMan Transport Media |
| Product Number | A-CA-02203-00 |
| Manufacturer/ Representative | Manufacturer: MES Medical Electronic Systems, Ltd 20 Alon Hatavor Street Zone 6 Caesarea Industrial Park 3088900 ISRAEL |
| Recommended use | QwikCheck MaleMan Transport Media is for in vitro diagnostic use only by professionals. |
| Section 2: Hazard Identification | |
| Classification of the substance or mixture | Gentamicin - S GHS Classification Reproductive toxicity: Category 1 A Specific target organ toxicity: Category 1 (Kidney, inner ear) - repeated exposure (Oral) GHS label elements Hazard pictograms: Signal Word: Danger Hazard Statements: H360D May damage the unborn child. H372 Causes damage to organs (Kidney, inner ear) through prolonged or repeated exposure if swallowed. Precautionary Statements: Provention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe mist or vapors. P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. Response: P308 + P313 F exposed or concerned: Get medical advice/ attention. Storage: P405 Store locked up. Penicillin G Appearance: White crystalline powder Signal Word: DANGER Statement of Hazard: May cause allergic/asthmatic symptoms or breathing difficulties if inhaled. May cause allergic skin reaction. Additional Hazard Information: Short Term Individuals who are allergic to penicillin antibiotics could have allergic reaction, possibly severe. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted. Known Clinical Effects: May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience cortact or systemic hypersensitivity and anaphylaxis upon exposure to this drug. EU Indication of danger: Harmful EU Hazard Symbols: EU Risk Phrases: R42/43 - May cause ensitization by inhalation and skin contact. Trisk Provoscory and the appropriate therapy instituted. CAS No 1185-53-1 Classification under 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200) This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard |



D-Glucose

CAS No 50-99-7

Classification according to Regulation (EC) No 1272/2008 (CLP)

This substance does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC.

Labelling according to Regulation (EC) No 1272/2008 (CLP): not required

Other hazards

Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.

D-Fructose

CAS No 57-48-7

Classification of the substance or mixture Classification acc. to GHS:

This substance does not meet the criteria for classification.

Label elements: Labelling not required

Other hazards

Results of PBT and vPvB assessment:

According to the results of its assessment, this substance is not a PBT or a vPvB.

Section 3: Composition/Information on Ingredients

Mixtures

Glucose anhydrous, D-Fructose, TRIS, Citric Acid anhydrous, Gentamycin-S, Penicillin G

Section 4: First-Aid Measures

General advice: Consult a physician. Refer to this safety data sheet to the doctor in attendance. **Inhalation**: Remove to fresh air. If not breathing, institute artificial respiration. Consult a physician. **Eyes**: Flush eyes immediately with copious amounts of water. Seek medical attention if symptoms occur.

Skin: Wash with soap and water after each contact. Seek medical attention if symptoms occur.

Ingestion: Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

Most important symptoms and effects, both acute and delayed: Described in the labeling (see Section 2) and/or in section 11.

Section 5: Fire-Fighting Measures

Extinguishing media: Suitable extinguishing media. Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special hazards arising from the substance or mixture: No data available.

Advice for firefighters: No data available.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Avoid breathing dust. Ensure adequate ventilation. For personal protection see section 8.

Environmental precautions: Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Do not discharge into environment. **Methods and materials for containment and cleaning up:** Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

Section 7: Handling and Storage

Precautions for safe handling: Avoid contact with skin and eyes. Avoid inhalation of vapor or mist. For precautions see section 2. Good laboratory practices should be followed, hand protection with gloves, clothing protection with laboratory coat - routine lab protection. **Conditions for safe storage, including any incompatibilities:** Store at refrigeration. Keep containers tightly closed in a dry and well-ventilated place.

Section 8: Exposure Controls/Personal Protection

Exposure controls: Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection: Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection: Wear laboratory quality (EU Directive 89/686/EEC and the standard EN 374) protective gloves when handling. Dispose of contaminated gloves in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Full contact Material: Nitrile rubber. Minimum layer thickness: 0,11 mm. Break through time: 480 min. Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M).

Splash contact material: Nitrile rubber. Minimum layer thickness: 0,11 mm. Break through time: 480 min. Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M). Data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de, test method: EN374. If used in solution, or mixed with other substances, and under conditions which differ from EN 374. contact the supplier of the CE approved gloves.

Body Protection: Laboratory gown/gloves for very low concentration in the workplace.

Respiratory protection: Due to very low concentration and minimal exposure time, mask and optional protective hood are recommended.

Control of environmental exposure: If safe, prevent further leakage/spillage. Do not let product enter drains or be discharged into the environment.

Section 9: Physical and Chemical Properties

Information on basic physical and chemical properties

- Appearance Form: liquid
- Odor/Odor Threshold: no data available
- pH / Viscosity: no data available
- Melting point/freezing point / Initial boiling point and boiling range: no data available
- Flash point: no data available
- Evaporation rate: no data available
- Flammability (solid, gas)/Upper/lower flammability or explosive limits: no data available
- Vapor pressure/density: no data available
- Relative density: no data available
- Water solubility / Partition coefficient: no data available
- Auto-ignition temperature: no data available
- Decomposition temperature: no data available
- Explosive/Oxidizing properties: no data available

Section 10: Stability and Reactivity

Reactivity: no data available

Chemical stability: Stable under recommended storage conditions.

Possibility of hazardous reactions: no data available

Conditions to avoid: no data available.

Hazardous decomposition products: Nature of decomposition products not known.

Other decomposition products: no data available

In the event of fire: see section 5

Section 11: Toxicological Information

Information on toxicological effects

Acute toxicity: no data available

Skin corrosion/irritation: no data available

Serious eye damage/eye irritation: no data available Respiratory or skin sensitisation: no data available

Germ cell mutagenicity: no data available Carcinogenicity IARC: no data available Reproductive toxicity: no data available

Specific target organ toxicity - single exposure: no data available Specific target organ toxicity - repeated exposure: no data available

Aspiration hazard: no data available Additional Information RTECS: not available

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Section 12: Ecological information

Toxicity: no data available

Persistence and degradability: no data available Bioaccumulative potential: no data available

Mobility in soil: no data available

Results of PBT and vPvB assessment: PBT/vPvB assessment not available as chemical safety assessment not required/ not conducted

Other adverse effects: no data available

Section 13: Disposal considerations

Provide adequate hazardous waste disposal based on the federal, provincial, or local regulations which must be followed. The appropriate authorities for your area should be contacted for this information. Dispose of surplus products and those that cannot be recycled via a licensed waste disposal contractor.

Section 14: Transport information

UN number:

- ADR/RID: -
- IMDG: -
- IATA: -

UN proper shipping name

- ADR/RID: Not dangerous goods
- IMDG: Not dangerous goods
- IATA: Not dangerous goods

Transport hazard class(es)

- ADR/RID: -
- IMDG: -
- IATA: -

Packaging group

- ADR/RID: -
- IMDG: -
- IATA: -

Environmental hazards

- ADR/RID: no
- IMDG Marine pollutant: no
- IATA: no

Special precautions for user: no data available

Section 15: Regulatory information

This product complies with regulations:

Complies with Regulation (EC) No. 1907/2006 (REACH), Annex II, and subsequent amendments introduced by Commission Regulation (EU) No. 2020/878

<u>Australian sponsor:</u> Acrapack PTY LTD Emergency Phone: +61 7 56410159 / +61 7 54490087

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Section 16: Additional Comments

Full text of H-Statements referred to under sections 2 and 3

H372 Causes damage to organs (Kidney, inner ear) through prolonged or repeated exposure if swallowed.

H319 serious eye damage/eye irritation

May cause allergic or asthmatic symptoms or breathing difficulties if inhaled. May cause allergic skin reaction.

The information presented above is correct to the best of our knowledge and Medical Electronic Systems does not claim that the information is all-inclusive but recommends that it should be used as a guide. Medical Electronic Systems shall not be held liable for any damage resulting from handling or from contact with the product.