



## SAFETY DATA SHEET

### Section 1: Identification

|                              |                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Product identifier</b>    | QwikCheck™ Dilution Kit                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Product number</b>        | 0800                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Manufacturer/supplier</b> | Medical Electronic Systems<br>5757 West Century Blvd. Suite #805, Los Angeles, CA 90045<br>Tel: 310 670-9066<br>Fax: 310 670-9069<br>Web: <a href="http://www.mes-global.com">www.mes-global.com</a>                                                                                                                                                                                                                                  |
| <b>Recommended use</b>       | The QwikCheck™ Dilution kit is used to dilute semen prior to automated or manual semen testing, when indicated. It is also used for sample preparation. The dilution media is Earle's balanced salt solution which contains ingredients known to support sperm motility and viability. It is recommended by WHO for semen sample preparation (WHO 2010, 5th edition manual, page 163). The product is intended for in vitro use only. |

### Section 2: Hazard(s) Identification

|                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|---------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Classification of the substance or mixture</b> | Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.<br>Not a hazardous substance or mixture according to EC-directives 67/548/EEC or 1999/45/EC.                                                                                                                                                                                                                                                                            |
| <b>Label elements</b>                             | <b>Labeling according Regulation (EC) No 1272/2008</b><br>Pictogram: none<br>Signal word: none<br>Hazard statement(s): none<br>Precautionary statement(s): none<br>Supplemental Hazard Statements: none<br>Safety data sheet available on request.<br><br><b>According to European Directive 67/548/EEC as amended</b><br>Hazard symbol(s): none<br>R-phrases: none<br>S-phrases: none<br>Safety data sheet available on request for professional users. |
| <b>Other hazards</b>                              | None                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

### Section 3: Composition/Information of Ingredients

|                 |                                                                        |                                            |               |
|-----------------|------------------------------------------------------------------------|--------------------------------------------|---------------|
| <b>Mixtures</b> | <b>Hazardous ingredients according to Regulation (EC) No 1272/2008</b> |                                            |               |
|                 | Component                                                              | Classification                             | Concentration |
|                 | Calcium chloride dihydrate<br>CAS-No. 10035-04-8                       | Skin Irrit. 2; Eye Irrit. 2;<br>H315, H319 | <10%          |
|                 | <b>Hazardous ingredients according to Directive 1999/45/EC</b>         |                                            |               |
|                 | Component                                                              | Classification                             | Concentration |
|                 | Calcium chloride dihydrate<br>CAS-No. 10035-04-8                       | Xi, R36                                    | <10%          |

### Section 4: First-Aid Measures

**General advice:** Consult a physician. Show this safety data sheet to the doctor in attendance.  
**Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Consult a physician.  
**Eyes:** In case of contact, 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:** Wear self contained breathing apparatus for fire-fighting if necessary.  
**Further information:** No data available.



## Section 6: Accidental Release Measures

**Personal precautions, protective equipment and emergency procedures:** Use personal protective equipment. 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. Discharge into the environment must be avoided.

**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:** For precautions see section 2.

**Conditions for safe storage, including any incompatibilities:** Store at room temperature. Keep containers tightly closed in a dry and well-ventilated place. Stable and show no loss of expected performance characteristics after transport/storage over a period of 72 hours at the temperature range of -20°C to +37°C.

## 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.

**Skin protection:** Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

**Body Protection:** Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

**Respiratory protection:** Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

**Control of environmental exposure:** Do not let product enter drains. Discharge into the environment must be avoided.

## Section 9: Physical and Chemical Properties

### Information on basic physical and chemical properties

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

Incompatible materials: strong oxidizing agents

Hazardous decomposition products: no data available

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 sensitization: no data available  
Germ cell mutagenicity: no data available  
Carcinogenicity IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.  
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

Persistence and degradability: no data available  
Bioaccumulation: Bioaccumulation is not expected to be significant. This product is readily biodegradable.  
Aquatic toxicity: no data available  
Ecotoxicity effects: no data available  
Mobility in soil: no data available  
Other adverse effects: no data available

## Section 13: Disposal considerations

### Waste treatment methods

Product: Offer surplus and non-recyclable solutions to a licensed disposal company.  
Contaminated packaging: Dispose of as unused product. The transportation, storage, treatment and disposal of this waste material must be conducted in compliance with Local regulations.

## 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:

CE: IVD 98\79\EC

FDA: Exempt

Health Canada: # 6658

### Section 16: Additional Comments

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

Eye Irrit.: Eye irritation

H315: Causes skin irritation.

H319: Causes serious eye irritation.

Skin Irrit.: Skin irritation

**Full text of R-phrases referred to under sections 2 and 3**

Xi: Irritant

R36: Irritating to eyes

All 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.