



## SAFETY DATA SHEET

Section 1: Identification	
Product identifier	QwikCheck™ Test Strips
Product number	0700 A-CA-01681-00
Manufacturer/supplier	Medical Electronic Systems 5757 West Century Blvd. Suite #805, Los Angeles, CA 90045 Tel: 310 670-9066 Fax: 310 670-9069 Web: <a href="http://www.mes-global.com">www.mes-global.com</a>
Recommended use	QwikCheck™ Test Strips are for in vitro diagnostic use for the determination of pH and leukocytes (WBCs) in semen. The test is semi-quantitative.
Section 2: Hazard Identification	
Classification of the substance or mixture	Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008. This product is not classified as dangerous according to Directive 67/548/EEC.
Label elements	The product does not need to be labeled in accordance with EC directives or respective national laws.
Other hazards	None
Section 3: Composition/Information on Ingredients	
Mixtures	Buffered salts, enzymes, pH indicators on plastic strips. Other components either non-hazardous or at concentrations below that requiring hazardous listing
Section 4: First-Aid Measures	
<p><b>Inhalation:</b> If breathed in, move person into fresh air. If not breathing, give artificial respiration. <b>Eyes:</b> Flush eyes with water as a precaution. <b>Skin:</b> Wash with soap and water after each contact. <b>Ingestion:</b> Never give anything by mouth to an unconscious person. Rinse mouth with water. <b>Most important symptoms and effects, both acute and delayed:</b> The most important known symptoms and effects are described in the labeling (see Section 2) and/or in section 11.</p>	
Section 5: Fire-Fighting Measures	
<p><b>Extinguishing media:</b> Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide. <b>Special hazards arising from the substance or mixture:</b> carbon oxides, hydrogen bromide gas. <b>Advice for firefighters:</b> Wear self contained breathing apparatus for fire-fighting if necessary. <b>Further information:</b> No data available.</p>	
Section 6: Accidental Release Measures	
<p><b>Personal precautions, protective equipment and emergency procedures:</b> Use personal protective equipment. For personal protection see section 8. <b>Environmental precautions:</b> Do not let product enter drains. <b>Methods and materials for containment and cleaning up:</b> Pick up. Keep in suitable, closed containers for disposal.</p>	
Section 7: Handling and Storage	



**Precautions for safe handling:** Normal measures for preventive fire protection. 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:** General industrial hygiene practice.

**Personal protective equipment:**

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

**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:** Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

**Respiratory protection:** Respiratory protection is not required.

**Control of environmental exposure:** Do not let product enter drains.

### Section 9: Physical and Chemical Properties

**Information on basic physical and chemical properties**

- Appearance Form: solid
- 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 properties: no data available
- 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  
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 sensitisation: no data available

Germ cell mutagenicity: no data available

Carcinogenicity IARC: No component of this product present at levels  $\geq 0.1\%$  is identified as a 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: LM5800000

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: not determined  
Aquatic toxicity: no data available  
Ecotoxicity effects: no data available  
Mobility in soil: no data available  
Results of PBT and vPvB assessment: no data available

Other adverse effects: no data available

### Section 13: Disposal considerations

#### Waste from residues / unused products:

Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Residue from fires extinguished with this material may be hazardous

### 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: # K063864  
Health Canada: # 95821

### Section 16: Additional Comments

NA

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.