



SAFETY DATA SHEET

Section 1: Identification	
Product identifier	QwikCheck™ Test Strips
Product number	0700 A-CA-01681-00
Manufacturer/ Representative	Manufacturer: MES Medical Electronic Systems, Ltd 20 Alon Hatavor Street Zone 6 Caesarea Industrial Park 3088900 ISRAEL
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	
Inhalation: If breathed in, move person into fresh air. If not breathing, give artificial respiration. Eyes: Flush eyes with water as a precaution. Skin: Wash with soap and water after each contact. Ingestion: Never give anything by mouth to an unconscious person. Rinse mouth with water. Most important symptoms and effects, both acute and delayed: The most important known symptoms and effects are described in the labeling (see Section 2) and/or in section 11.	
Section 5: Fire-Fighting Measures	
Extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide. Special hazards arising from the substance or mixture: carbon oxides, hydrogen bromide gas. 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. For personal protection see section 8. Environmental precautions: Do not let product enter drains. Methods and materials for containment and cleaning up: Pick up. Keep in suitable, closed containers for disposal.	

Revision date: 14 AUG 2025

Reviewed and approved by: Taly Vider, Regulatory Affairs and IP Director



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: IVDD 98\79\EC, IVDR (EU) 2017/746

FDA: # K063864

Health Canada: # 95821

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

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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.