





## SAFETY DATA SHEET

### Section 1: Identification

<b>Product Identifier</b>	QwikCheck™ DNA Fragmentation Index (DFI) Kit
<b>Product Number</b>	A-CA-01873-00
<b>Manufacturer/supplier</b>	Medical Electronic Systems 6345 Balboa Blvd. # 185 Encino, CA 91316 Tel: 310 670-9066 Web: <a href="http://www.mes-global.com">www.mes-global.com</a>
<b>Recommended use</b>	The QwikCheck DFI Kit is an in-vitro use, diagnostic kit for testing DNA Fragmentation Index of spermatozoa in semen samples by Sperm Chromatin Dispersion (SCD) method. For in vitro diagnostic use only by professionals.

### Section 2: Hazard Identification

<b>Classification of the substance or mixture</b>	Contains highly diluted Triton X-100 and Sodium Hydroxide, DTT <b>Classification according to Regulation (EC) No 1272/2008</b> <u>Sodium Hydroxide</u> Corrosive to Metals (Category 1), H290 Skin corrosion (Sub-category 1A), H314 Serious eye damage (Category 1), H318 <u>Triton X 100</u> Skin irritation, Category 1B, H314 Acute toxicity (oral), Category 4, H302 Hazardous to the aquatic, environment — Acute Hazard, Category 1, H400 For the full text of the H-Statements mentioned in this Section, see Section 16. <u>DTT:</u> Acute toxicity, Oral (Category 4), H302 Skin irritation (Category 2), H315 Serious eye damage (Category 1), H318 <b>Classification according to EU Directives 67/548/EEC or 1999/45/EC</b> Xn; R22 C; R34 Xi; R41 N; R50 For the full text of the R-phrases mentioned in this Section, see Section 16.
<b>Label elements</b>	<b>Labeling according Regulation (EC) No 1272/2008</b>  Pictogram:  Signal word: Warning Hazard statement(s): H302: Harmful if swallowed. H315 Causes skin irritation. H314 - Causes severe skin burns and eye damage H400 - Toxic to aquatic life Precautionary statement(s): P234 Keep only in original packaging. P260 Do not breathe dust. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. P303 + P361 + P353 IF ON SKIN (or hair): Remove all contaminated clothing immediately and rinse skin with water. P304 + P340 + P310 IF INHALED: Remove person to fresh air. Immediately call a POISON CENTER/ doctor. P305 + P351 + P338 IF IN EYES: Repeatedly rinse cautiously with water for several minutes. Remove contact lenses if possible. Supplemental Hazard Statements: none  <b>According to European Directive 67/548/EEC as amended</b> Hazard symbol(s): Xn Harmful   R-phrases(s): R21/22: Harmful when in contact with skin or swallowed. R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. S-phrases(s): S36/37: Wear suitable protective clothing and gloves. S61: Avoid release to the environment. Refer to special instructions/ Safety data sheets

### Section 3: Composition/Information on Ingredients

<b>Mixtures</b>	Agarose 9012-36-6 Free of Toxic Classification Sodium Chloride 7647-14-5 Free of Toxic Classification Tris 77-86-1 Free of Toxic Classification Dithiothreitol (DTT) 3483-12-3 Acute Tox. 4; Skin Irrit. 2; Eye Dam. 1; H302, H315, H318 Triton X 100 , 9002-93-1, R-22 R41 For the full text of the H-Statements and R-Phrases mentioned in this Section, see Section 16. The specific chemical identity of ingredients and/or exact percentage of composition is withheld as a trade secret.
-----------------	---

#### 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 room temperature. 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. f  
**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: liquids and a powder reconstituted with provided solutions before use at the customer site.
- 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: n-octanol/water: 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.  
 Incompatible materials: Heavy metals may form extremely explosive azides in large concentrations.  
 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 component of this product present at levels  $\geq 1\%$  is identified as probable, possible or a 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

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: EC No. 1907/2006

## Section 16: Additional Comments

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

Eye Irrit.: Eye irritation  
 Acute Tox. 4; Acute Toxicity Category 4  
 Skin Irrit. 2; Skin Irritation Category 2  
 Eye Dam. 1; Eye Damage Category 1  
 H315: Causes skin irritation.  
 H318: Causes serious eye damage.  
 H319: Causes serious eye irritation.  
 H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
 H335: May cause respiratory irritation.  
 Resp. Sens.: Respiratory sensitization  
 Skin Irrit.: Skin irritation  
 STOT SE: Specific target organ toxicity - single exposure

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

Xn: Harmful  
 R36/37/38: Irritating to eyes, respiratory system and skin  
 R42: May cause sensitization by inhalation.



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.