

SAFETY DATA SHEET

Section 1: Identification	
Product Identifier	QwikCheck™ DNA Fragmentation Index (DFI) Kit
Product Number	A-CA-01873-00
Manufacturer/ Representative	Manufacturer: MES Medical Electronic Systems, Ltd 20 Alon Hatavor Street Zone 6 Caesarea Industrial Park 3088900 ISRAEL
Recommended use	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	
Classification of the substance or mixture	Contains highly diluted Triton X-100 and Tris(2-carboxyethyl)phosphine hydrochloride (TCEP) Classification according to Regulation (EC) No 1272/2008 <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>TCEP:</u> Skin corrosion, (Sub-category 1B), H314: Causes severe skin burns and eye damage. Serious eye damage (Category 1), H318: Causes serious eye damage. Classification according to EU Directives 67/548/EEC or 1999/45/EC Xn; R22 C; R34 Xi; R41 N; R50 For the full text of the R-phrases mentioned in this Section, see Section 16.

Label elements	Labeling according Regulation (EC) No 1272/2008  Pictogram Signal Word: Danger Hazard Statements H314 Causes severe skin burns and eye damage. Precautionary Statements P260 Do not breathe dust. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P363 Wash contaminated clothing before reuse. Supplemental Hazard Statements: None According to European Directive 67/548/EEC as amended 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	
Mixtures	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 Tris(2-carboxyethyl)phosphine hydrochloride (TCEP), 51805-45-9, Skin Corr. 1B; Eye Dam.1; H314, 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:

CE: IVDR (EU) 2017/746

FDA: Exempt

Health Canada: # 109508

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

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.