



SAFETY DATA SHEET

| Section 1: Identification | |
|---|--|
| Product Identifier | QwikCheck™ Test Strip Quality Control |
| Product Number | A-CA-01752-00 |
| Manufacturer/ Representative | Manufacturer: MES Medical Electronic Systems, Ltd 20 Alon Hatavor Street Zone 6 Caesarea Industrial Park 3088900 ISRAEL |
| Recommended use | QwikCheck™ Test Strip QC is used to validate QwikCheck™ Test Strips that assess pH and leukocyte (WBC) levels in human semen. The QC results are determined by placing the QC media onto the QwikCheck Test Strip's pH and WBC patches and comparing the developed strip colors to the color chart on the QwikCheck Test Strips. QwikCheck Test Strip QC is for in vitro diagnostic use only by professionals. |
| Section 2: Hazard Identification | |
| Classification of the substance or mixture | Contains highly diluted Sodium Azid. Classification according to Regulation (EC) No 1272/2008 Acute toxicity, Oral (Category 4), H302 Chronic aquatic toxicity (Category 3), H412 For the full text of the H-Statements mentioned in this Section, see Section 16. Classification according to EU Directives 67/548/EEC or 1999/45/EC Xn Harmful R21/22 R52/53 For the full text of the R-phrases mentioned in this Section, see Section 16. |

Revision date: 14 AUG 2025

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

Label elements

Labeling according Regulation (EC) No 1272/2008

Pictogram: 

Signal word: Warning

Hazard statement(s):

H302: Harmful if swallowed.

H412: Harmful to aquatic life with long lasting effects.

Precautionary statement(s):

P273: Avoid release to the environment.

Supplemental Hazard Statements: none

According to European Directive 67/548/EEC as amended

Hazard symbol(s): Xn Harmful



R-phrases(s):

R21/22: Harmful in contact with skin and if 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

Hazardous ingredients according to Regulation (EC) No 1272/2008

| Component | Classification | Concentration |
|--------------------------------|--|---------------|
| Sodium Azide, CAS # 26628-22-8 | Acute Tox. 2; Acute Tox. 1; Aquatic Acute 1; Aquatic Chronic 1; H300 + H310, H410, EUH032 | <1% |

Hazardous ingredients according to Directive 1999/45/EC

| Component | Classification | Concentration |
|--------------------------------|------------------------------------|---------------|
| Sodium Azide, CAS # 26628-22-8 | T+, N, R27 - R28 - R32 - R50/53 | <1% |

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. 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.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Avoid breathing vapors, mist or gas. 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: 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.

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. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

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: 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: powder reconstituted with distilled or deionized water 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.

Hazardous decomposition products: Hazardous decomposition products formed under fire conditions. 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.



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: Exempt

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

Australian sponsor: Acrapack PTY LTD

Emergency Phone: +61 7 56410159 / +61 7 54490087

www.acrapack.com.au

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.

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.