

SAFETY DATA SHEET

	QwikCheck™ Liquefaction Kit			
Due do et monde en				
Product number 09	900, A-CA-01698-00			
Manufacturer/ 20 Representative Zo	Manufacturer: MES Medical Electronic Systems, Ltd 0 Alon Hatavor Street one 6 Caesarea Industrial Park 088900 ISRAEL			
Recommended use th	The QwikCheck™ Liquefaction Kit is used to accelerate the liquefaction of viscous semen samples in order to prepare them for automated or manual semen analysis. Samples that remain viscous 30 minutes or more after collection may not be accurately analyzed for sperm motility and concentration. For in-vitro use only.			
Section 2: Hazard(s) Identification				
Classification of the substance or mixture Civilian Signature Substance or Mixture Civilian Signature Substance Sub	Classification according to Regulation (EC) No 1272/2008 Eye irritation: (Category 2), H319 Expecific target organ toxicity - single exposure: (Category 3), H335 Eximitration: (Category 2), H315 Experimental Exper			
Pi Si H: H: Label elements Pi P: ar P:	Abeling according Regulation (EC) No 1272/2008 Pictogram Signal word: Danger Idazard statement(s) Idazard s			
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Section 3:	Composition	/Information	of Ingredients
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Hazardous ingredients according to Regulation (EC) No 1272/2008

Component	Classification	Concentration
Chymotrypsin CAS-No. 9004-07-3	Skin Irrit. 2; Eye Irrit. 2; Resp. Sens. 1; STOT SE 3; H315, H319, H334, H335	<=100%

Hazardous ingredients according to Directive 1999/45/EC

Component	Classification	Concentration
Chymotrypsin CAS-No. 9004-07-3	Xn, R36/37/38 - R42	<=100%

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: 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: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special hazards arising from the substance or mixture: No data available.

Advice for fire-fighters: 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 dust. Ensure adequate ventilation. For personal protection see section 8.

Environmental precautions: Use and dispose of without creating dust. Do not let product enter drains. Avoid discharging material into the environment

Methods and materials for containment and cleaning up: Use and dispose of without creating dust. Keep in suitable, closed containers for disposal.

Section 7: Handling and Storage

Precautions for safe handling: Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. 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

Mixtures

Appropriate engineering 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.

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: For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator. For higher level protection use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure: Do not let product enter drains. Discharge into the environment must be avoided.

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Section 9: Physical and Chemical Properties

Information on basic physical and chemical properties

- Appearance Form: powder, lyophilized
- 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: LD50
Oral - rat: > 4.000 mg/kg
Inhalation: no data available

Skin corrosion/irritation: no data available

Serious eye damage/eye irritation: no data available Respiratory or skin sensitization: no data available

Germ cell mutagenicity: no data available

Carcinogenicity IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed

human carcinogen by IARC.

Reproductive toxicity: no data available

Specific target organ toxicity - single exposure: may cause respiratory irritation.

Specific target organ toxicity - repeated exposure: no data available

Aspiration hazard: no data available

Additional Information: RTECS: GC3050000

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

Waste treatment methods Product Offer surplus and non-recyclable solutions to a licensed disposal company.

Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging Dispose of as unused product.

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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: # 6658

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

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.

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