



SAFETY DATA SHEET

Section 1: Identification	
Product identifier	SQA-V Cleaning Kit, SQA-Vision Cleaning Kit, SQA-iO Cleaning Kit.
Product number	0113, 0115, IO-CA-01680-00, IO-CA-01783-00
Manufacturer/ Representative	Manufacturer: MES Medical Electronic Systems, Ltd 20 Alon Hatavor Street Zone 6 Caesarea Industrial Park 3088900 ISRAEL
Recommended use	The SQA-V, SQA-Vision, SQA-iO Cleaning Kits are intended for both routine and contamination cleaning of the labeled devices.
Section 2: Hazard(s) Identification	
Classification of the substance or mixture	Classification according to Regulation (EC) No 1272/2008 Flammable liquids (Category 2), H225 Classification according to EU Directives 67/548/EEC or 1999/45/EC F, Highly flammable, R11
Label elements	Labeling according Regulation (EC) No 1272/2008 Pictogram  Signal word: Danger Hazard statement(s) H225: Highly flammable liquid and vapor. Precautionary statement(s) P210: Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Supplemental Hazard Statements: none
Other hazards	None
Section 3: Composition/Information of Ingredients	
Mixtures	- Ethanol (CAS No.64-17-5) - 50% - Tween 20 (CAS No.9005-64-5) - 0.5%
Section 4: First-Aid Measures	
General advice: Consult a physician. Show this safety data sheet to the doctor in attendance. Inhalation: If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician. Eyes: Rinse thoroughly with a copious amount of water for at least 15 minutes and consult a physician. Skin: Wash off with soap and a copious amount of water. Consult a physician. Ingestion: Do NOT induce vomiting. Rinse mouth with water – only if the person is conscious. Consult a physician. Most important symptoms and effects, both acute and delayed: Refer to the labeling (see Section 2 and/or 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 firefighters: Wear self contained breathing apparatus for fire-fighting if necessary. Further information: Use water spray to cool unopened containers.	

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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. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapors accumulating to form explosive concentrations. Vapors can accumulate in low areas. For personal protection see section 8.

Environmental precautions: Do not let product enter drains.

Methods and materials for containment and cleaning up: Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations.

Section 7: Handling and Storage

Precautions for safe handling: Avoid contact with skin and eyes. Avoid inhalation of vapor or mist. Keep away from sources of ignition - No smoking. Take measures to prevent the build-up of electrostatic charge. 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.

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: 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: Do not let product enter drains.



Section 9: Physical and Chemical Properties

Information on basic physical and chemical properties

- a) Appearance Form: liquid, clear, colorless
- b) Odor: no data available
- c) Odor Threshold: no data available
- d) pH: no data available
- e) Melting point/freezing point: no data available
- f) Initial boiling point and boiling range: no data available
- g) Flash point: no data available
- h) Evaporation rate: no data available
- i) Flammability (solid, gas): no data available
- j) Upper/lower flammability or explosive limits: no data available
- k) Vapor pressure: no data available
- l) Vapor density: no data available
- m) Relative density: no data available
- n) Water solubility: no data available
- o) Partition coefficient: n-octanol/water: no data available
- p) Auto-ignition temperature: no data available
- q) Decomposition temperature: no data available
- r) Viscosity: no data available
- s) Explosive properties: no data available
- t) Oxidizing properties: no data available

Other safety information: 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: Heat, flames and sparks. Extremes of temperature and direct sunlight.
Incompatible materials: Alkali metals, Oxidizing agents, Peroxides
Hazardous decomposition products: no data available
Other decomposition products: no data available
In the event of fire: see Section 5

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Section 11: Toxicological Information

Information on toxicological effects

Acute toxicity LD50

Oral - Rat - 7.060 mg/kg

Remarks: Lungs, Thorax, or Respiration: Other changes.

LC50 Inhalation - Rat - 10 h - 20000 ppm

Skin corrosion/irritation

Skin - Rabbit

Result: No skin irritation - 24 h

(OECD Test Guideline 404)

Serious eye damage/eye irritation

Eyes - Rabbit

Result: Mild eye irritation - 24 h

(OECD Test Guideline 405)

Respiratory or skin sensitization: No data available

Germ cell mutagenicity: No data available

Carcinogenicity

Carcinogenicity - Mouse - Oral

Tumorigenic: Equivocal tumorigenic agent by RTECS criteria.

Liver: Tumors. Blood: Lymphomas including Hodgkin's disease.

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

Reproductive toxicity - Human - female - Oral Effects on Newborn: Apgar score (human only).

Effects on Newborn: Other neonatal measures or effects.

Effects on Newborn: Drug dependence.

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: KQ6300000

Central nervous system depression, narcosis, Damage to the heart.

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Section 12: Ecological information

The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

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 treatment methods

Product: Offer surplus and non-recyclable solutions to a licensed disposal company.
Contaminated packaging: Dispose of as unused product.

Section 14: Transport information

UN number:

- ADR/RID: 1170
- IMDG: 1170
- IATA: 1170

UN proper shipping name

- ADR/RID: ETHANOL
- IMDG: ETHANOL
- IATA: ETHANOL

Transport hazard class(es)

- ADR/RID: 3
- IMDG: 3
- IATA: 3

Packaging group

- ADR/RID: II
- IMDG: II
- IATA: II

Environmental hazards

- ADR/RID: no
- IMDG Marine pollutant: no
- IATA: no

Special precautions for user: no data available

*****This product is an exception as it is packed in small quantities (30ml) and combined packaging. No transport limitations should be applied to it.**

Section 15: Regulatory

This product complies with regulations:

CE: IVDR (EU) 2017/746

FDA: NA - NON MEDICAL DEVICE

Health Canada: NA - NON MEDICAL DEVICE

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 Information

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

H225: Highly flammable liquid and vapor

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Full text of R-Statements referred to under sections 2 and 3.

R11: Highly flammable

Full text of P-Statements referred to under sections 2 and 3.

P210: Keep away from heat/sparks/open flames/hot surfaces. - No smoking

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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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