




## SAFETY DATA SHEET

Section 1: Identification	
Product identifier	SQA-V, SQA-Vision and SQA II Cleaning Kit
Product number	0113; 0115; 0121; 0116; 0625; 0117; PEB-A-00597-00
Manufacturer/supplier	Medical Electronic Systems 5757 West Century Blvd. Suite #805, Los Angeles, CA 90045 Tel: 310 670-9066 Fax: 310 670-9069 Web: <a href="http://www.mes-global.com">www.mes-global.com</a>
Recommended use	The SQA-V, SQA-Vision and SQA II 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	<b>Classification according to Regulation (EC) No 1272/2008</b> Flammable liquids (Category 2), H225 <b>Classification according to EU Directives 67/548/EEC or 1999/45/EC</b> F, Highly flammable, R11
Label elements	<b>Labeling according Regulation (EC) No 1272/2008</b>  Pictogram Signal word: Danger <b>Hazard statement(s)</b> H225: Highly flammable liquid and vapor. <b>Precautionary statement(s)</b> 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	<ul style="list-style-type: none"><li>Ethanol (CAS No.64-17-5) - 50%</li><li>Tween 20 (CAS No.9005-64-5) - 0.5%</li></ul>
Section 4: First-Aid Measures	
<b>General advice:</b> Consult a physician. Show this safety data sheet to the doctor in attendance. <b>Inhalation:</b> If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician. <b>Eyes:</b> Rinse thoroughly with a copious amount of water for at least 15 minutes and consult a physician. <b>Skin:</b> Wash off with soap and a copious amount of water. Consult a physician. <b>Ingestion:</b> Do NOT induce vomiting. Rinse mouth with water – only if the person is conscious. Consult a physician. <b>Most important symptoms and effects, both acute and delayed:</b> Refer to the labeling (see Section 2 and/or section 11).	
Section 5: Fire-Fighting Measures	
<b>Extinguishing media:</b> Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide. <b>Special hazards arising from the substance or mixture:</b> No data available. <b>Advice for firefighters:</b> Wear self contained breathing apparatus for fire-fighting if necessary. <b>Further information:</b> Use water spray to cool unopened containers.	



## 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

## 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.**

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This product complies with regulations:

CE: IVD 98\79\EC  
FDA: NA - NON MEDICAL DEVICE  
Health Canada: NA - NON MEDICAL DEVICE

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#### 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

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.