

## SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier**  
Trade name ASTUTE140® Electronic Quality Control (EQC) Device
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**  
Identified use(s) *In vitro* diagnostic medical device. For professional use only.
- 1.3 Details of the supplier of the safety data sheet**  
Company Identification Astute Medical, Inc.  
3550 General Atomics Ct.  
Building 2  
San Diego, CA 92121 USA  
Telephone +1 (858) 500-7000  
E-Mail (competent person) info@astutemedical.com
- 1.4 Emergency telephone number**  
Emergency Phone No. +1 (855) 807-2783

## SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture**
- Regulation (EC) No. 1272/2008 (CLP)** Not classified as hazardous.
- OSHA Hazard Communication Standard 29 CFR 1910.1200 (HazCom 2012) / GHS** Not classified as hazardous.
- 2.2 Label elements** No measures required.
- 2.3 Other hazards** None.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.1 Mixtures**
- Description: *In vitro* diagnostic medical device.
- Dangerous components: The product does not contain reportable quantities of dangerous components.
- Additional information None.

## SECTION 4: FIRST AID MEASURES

- 4.1 Description of first aid measures**
- Inhalation Not relevant for this material.  
Skin Contact No treatment necessary.  
Eye Contact Not relevant for this material.  
Ingestion Not relevant for this material.
- 4.2 Most important symptoms and effects, both acute and delayed** No data available.
- 4.3 Indication of the immediate medical attention and special treatment needed** No data available.

## SECTION 5: FIRE-FIGHTING MEASURES

- 5.1 Extinguishing media**  
Suitable Extinguishing Media CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

<b>5.2 Special hazards arising from the substance or mixture</b>	In case of fire, the following can be released: Carbon oxides (COx), Hazardous fumes.
<b>5.3 Advice for fire-fighters</b>	Use fire-extinguishing methods suitable to surrounding conditions. Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

<b>6.1 Personal precautions, protective equipment and emergency procedures</b>	No special requirements.
<b>6.2 Environmental precautions</b>	No special requirements.
<b>6.3 Methods and material for containment and cleaning up</b>	Collect material and dispose of as waste according to Section 13.
<b>6.4 Reference to other sections</b>	8, 13

## SECTION 7: HANDLING AND STORAGE

<b>7.1 Precautions for safe handling</b>	Avoid contact with skin and eyes. Keep out of reach of children. Wash hands before breaks and after work.
<b>7.2 Conditions for safe storage, including any incompatibilities</b>	Store in the original container at 15 to 25°C.
<b>7.3 Specific end use(s)</b>	Use as per instructions for use.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

<b>8.1 Control parameters</b>	
<b>8.1.1 Occupational Exposure Limits</b>	The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
<b>8.2 Exposure controls</b>	
<b>8.2.1 Appropriate engineering controls</b>	Not relevant for this material.
<b>8.2.2 Personal protection equipment</b>	
Eye/face protection	Safety Glasses
Hand protection	Disposable gloves.
Material of gloves:	Latex / natural rubber, Nitrile rubber
Penetration time of glove material:	Gloves resistance is not critical when the product is handled according to the instructions for use.
Body protection	Laboratory coat.
Respiratory protection	Not required under recommended use.
<b>8.2.3 Environmental Exposure Controls</b>	No special measures are required.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<b>9.1 Information on basic physical and chemical properties</b>	
Appearance	Solid.
Colour	Black and White.
Odour	No odour.
Odour Threshold (ppm)	No data available.
pH (Value)	No data available.
Melting Point (°C) / Freezing Point (°C)	No data available.
Boiling point/boiling range (°C):	No data available.
Flash Point (°C)	No data available.
Evaporation rate (BA = 1)	No data available.
Flammability (solid, gas)	No data available.
Explosive limit ranges	No data available.
Vapour Pressure (Pascal)	No data available.
Vapour Density (Air=1)	No data available.

Density (g/ml)	No data available.
Solubility (Water)	No data available.
Solubility (Other)	No data available.
Partition Coefficient (n-Octanol/water)	No data available.
Auto Ignition Temperature (°C)	No data available.
Decomposition Temperature (°C)	No data available.
Viscosity (mPa.s)	No data available.
Explosive properties	Not explosive.
Oxidising properties	Not oxidising
<b>9.2 Other information</b>	Not available

## SECTION 10: STABILITY AND REACTIVITY

<b>10.1 Reactivity</b>	No data available.
<b>10.2 Chemical stability</b>	The product is stable in accordance with the recommended storage conditions.
<b>10.3 Possibility of hazardous reactions</b>	None known. Hazardous polymerisation will not occur.
<b>10.4 Conditions to avoid</b>	None
<b>10.5 Incompatible materials</b>	No data available.
<b>10.6 Hazardous Decomposition Product(s)</b>	No data available.

## SECTION 11: TOXICOLOGICAL INFORMATION

<b>11.1 Information on toxicological effects</b>	
<b>11.1.2 Mixtures</b>	
Acute toxicity	No data available
Skin corrosion/irritation	No data available
Serious eye damage/irritation	No data available
Respiratory/skin sensitization	No data available
Germ cell mutagenicity	No data available
Carcinogenicity	No data available
Reproductive toxicity	No data available
STOT-single exposure	No data available
STOT-repeated exposure	No data available
Aspiration hazard	No data available
<b>Health Effects and Symptoms</b>	
Skin Contact	No significant harmful effects anticipated.
Eye Contact	No significant harmful effects anticipated.
Ingestion	No significant harmful effects anticipated.
<b>11.2 Other information</b>	No data available.

## SECTION 12: ECOLOGICAL INFORMATION

<b>12.1 Toxicity</b>	The product does not contain significant quantities of ingredients that are environmentally toxic.
<b>12.2 Persistence and degradability</b>	The device contains plastic and other components that are not readily degradable.
<b>12.3 Bioaccumulative potential</b>	No data available.
<b>12.4 Mobility in soil</b>	No data available.
<b>12.5 Results of PBT and vPvB assessment</b>	No data available.
<b>12.6 Other adverse effects</b>	No data available.

## SECTION 13: DISPOSAL CONSIDERATIONS

<b>13.1 Waste treatment methods</b>	
<b>Product:</b>	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the

relevant (local) authorities and/or an approved waste-disposal company for information.

**European waste catalogue:**

18 01 07.

**Packaging:**

Disposal should be in accordance with local, state or national legislation. Packaging materials may be recycled. Contact your local service providers for further information.

## SECTION 14: TRANSPORT INFORMATION

14.1	<b>UN number</b>	Not applicable.
14.2	<b>UN Proper Shipping Name</b>	Not applicable.
14.3	<b>Transport hazard class(es)</b>	Not classified as dangerous for transport.
14.4	<b>Packing Group</b>	Not applicable.
14.5	<b>Environmental hazards</b>	Not applicable.
14.6	<b>Special precautions for user</b>	Not applicable.
14.7	<b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.

## SECTION 15: REGULATORY INFORMATION

15.1	<b>Safety, health and environmental regulations/legislation specific for the substance or mixture</b>	In Vitro diagnostics medical devices directive 98/79/EC. OSHA Hazard Communication Standard 29 CFR 1910.1200 Consumer Product Safety Regulations 16 CFR 1600 IVD Product Labelling 21 CFR 809
	<b>Carcinogen listings</b>	
	IARC:	None of the ingredients is listed.
	NTP:	None of the ingredients is listed.
	ACGIH:	None of the ingredients is listed.
	OSHA:	None of the ingredients is listed.
	EPA:	None of the ingredients is listed.
	<b>Californian Proposition 65</b>	
	Chemicals known to cause cancer:	None of the ingredients is listed.
	Chemicals known to cause reproductive toxicity:	None of the ingredients is listed.
	<b>SARA</b>	
	Section 355 (extremely hazardous substances):	None of the ingredients is listed.
	Section 313 (specific toxic chemical listings):	None of the ingredients is listed.
15.2	<b>Chemical Safety Assessment</b>	Not applicable.

## SECTION 16: OTHER INFORMATION

### References:

Raw safety data sheets.

### Additional Information

Reason for update: SDS Compliance

Supersedes: PN: 300134 Rev D

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