

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)	<i>In vitro</i> 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

3.2 Mixtures	Description:	<i>In vitro</i> 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		None known.
4.3 Indication of the immediate medical attention and special treatment needed		None.

SECTION 5: FIRE-FIGHTING MEASURES

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| 5.1 Extinguishing media
Suitable Extinguishing Media | CO ₂ , powder or water spray. Fight larger fires with water spray or alcohol resistant foam. |
| 5.2 Special hazards arising from the substance or mixture | In case of fire, the following can be released: Carbon oxides (CO _x), Hazardous fumes. |
| 5.3 Advice for fire-fighters | 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

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

SECTION 7: HANDLING AND STORAGE

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| 7.1 Precautions for safe handling | Avoid contact with skin and eyes.
Keep out of reach of children.
Wash hands before breaks and after work. |
| 7.2 Conditions for safe storage, including any incompatibilities | Store in the original container at 18 to 25°C. |
| 7.3 Specific end use(s) | Use as per instructions for use. |

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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| 8.1 Control parameters | |
| 8.1.1 Occupational Exposure Limits | The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace. |
| 8.2 Exposure controls | |
| 8.2.1 Appropriate engineering controls | Not relevant for this material. |
| 8.2.2 Personal protection equipment | |
| ▶ Eye/face protection | Not normally required. |
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| Hand protection | Disposable gloves. |
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| 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 normally required. |
| 8.2.3 Environmental Exposure Controls | No special measures are required. |

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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| 9.1 Information on basic physical and chemical |
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properties	
Appearance	Solid.
Colour	Black and White.
Odour	No odour.
Odour Threshold (ppm)	Not applicable.
pH (Value)	Not determined.
Melting Point (°C) / Freezing Point (°C)	Not determined.
Boiling point/boiling range (°C):	Not applicable.
Flash Point (°C)	Not applicable.
Evaporation rate (BA = 1)	Not applicable.
Flammability (solid, gas)	Not determined.
Explosive limit ranges	Not applicable.
Vapour Pressure (Pascal)	Not applicable.
Vapour Density (Air=1)	Not applicable.
Density (g/ml)	Not determined.
Solubility (Water)	Not applicable.
Solubility (Other)	Not determined.
Partition Coefficient (n-Octanol/water)	Not determined.
Auto Ignition Temperature (°C)	Not determined.
Decomposition Temperature (°C)	Not determined.
Viscosity (mPa.s)	Not applicable.
Explosive properties	Not explosive.
Oxidising properties	Not oxidising
9.2 Other information	Not available

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity	None known.
10.2 Chemical stability	The product is stable in accordance with the recommended storage conditions.
10.3 Possibility of hazardous reactions	None known. Hazardous polymerisation will not occur.
10.4 Conditions to avoid	None
10.5 Incompatible materials	None known.
10.6 Hazardous Decomposition Product(s)	None known.

▶ SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.2 Mixtures

Acute toxicity	Based upon the available data, the classification criteria are not met.
Skin corrosion/irritation	Based upon the available data, the classification criteria are not met.
Serious eye damage/irritation	Based upon the available data, the classification criteria are not met.
Respiratory/skin sensitization	Based upon the available data, the classification criteria are not met.
Germ cell mutagenicity	Based upon the available data, the classification criteria are not met.
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Reproductive toxicity	Based upon the available data, the classification criteria are not met.
STOT-single exposure	Based upon the available data, the classification criteria are not met.
STOT-repeated exposure	Based upon the available data, the classification criteria are not met.
Aspiration hazard	Based upon the available data, the classification criteria are not met.

Health Effects and Symptoms

Skin Contact	No significant harmful effects anticipated.
Eye Contact	No significant harmful effects anticipated.
Ingestion	No significant harmful effects anticipated.

11.2 Other information Not applicable.

SECTION 12: ECOLOGICAL INFORMATION

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

SECTION 13: DISPOSAL CONSIDERATIONS

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

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	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
Carcinogen listings	
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.
Californian Proposition 65	
Chemicals known to cause cancer:	None of the ingredients is listed.

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

Chemicals known to cause reproductive toxicity: None of the ingredients is listed.
SARA
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 Chemical Safety Assessment Not applicable.

SECTION 16: OTHER INFORMATION

LEGEND

STOT Specific Target Organ Toxicity

References:

Raw material safety data sheets.

Additional Information

Reason for update: SECTION 2: SECTION 4: SECTION 6: SECTION 8:
SECTION 11: SECTION 15:
► Indicates altered section

Supersedes: PN: 300134 Rev C

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