

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

1.1 Product identifier	Trade name	US IVD 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

3.1 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		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 ₂ , powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
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| 5.2 Special hazards arising from the substance or mixture | In case of fire, the following can be released: Carbon oxides (COx), 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 | 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. |
| 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 properties | |
| 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
9.2 Other information	Not available

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity	No data available.
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	No data available.
10.6 Hazardous Decomposition Product(s)	No data available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.2 Mixtures

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

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	No data available.
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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 available.
12.4 Mobility in soil	No data available.
12.5 Results of PBT and vPvB assessment	No data available.
12.6 Other adverse effects	No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	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
Product:	

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.
	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

References:
Raw safety data sheets.

Additional Information

Reason for update: SDS Compliance

Supersedes: PN: 300134 Rev D

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