

**hc2 HPV/CT/GC**

<b>1 IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY</b>				
1.1 <u>Identification of the Product:</u>	<b>SPECIMEN TRANSPORT MEDIUM</b> <table border="1"> <tr> <td>MED</td> <td>SPEC</td> <td>TRANS</td> </tr> </table>	MED	SPEC	TRANS
MED	SPEC	TRANS		
1.2 <u>Identification of Company</u>	Digene Corporation 1201 Clopper Road Gaithersburg, MD 20878			
1.3 <u>Emergency Tel. No:</u>	Domestic (U.S.) +301-944-7000 (8:30 AM – 5 PM Eastern M-F) International (U.K.) +44 (20) 7348 3500 (9 AM – 6 PM Local U.K. Time M-F)			

**2 COMPOSITION/INFORMATION ON INGREDIENTS**

<u>Substance</u>	<u>CAS No.</u>	<u>% Present</u>	<u>Symbol(s)</u>	<u>EC</u> <u>R-Phrases</u>
Aliphatic amine hydrochloride	Proprietary	<10	Xn (Harmful)	22-36/38
Sodium azide*	26628-22-8	0.05	T <sup>+</sup> (Very toxic) and N (Dangerous for the environment)	28-32-50/53
Other components* & water	-	Up to 100	-	-

\*These components are at concentrations that do not meet EU or US OSHA criteria for classifying as dangerous or hazardous, respectively, under these regulations.

**3 HAZARDS IDENTIFICATION**

Based on percentages of hazardous ingredients in this product, this product is not classified as “dangerous” under EU Directives or hazardous under US OSHA Hazard Communication regulations.

**4 FIRST AID MEASURES**

- In case of swallowing - Wash out mouth thoroughly with water. Do not induce vomiting. If concerned, seek medical advice.
- In case of inhalation - Remove to fresh air. If concerned, seek medical advice.
- In case of contact with eyes - Rinse immediately with plenty of water for at least 15 minutes, avoiding contamination of unaffected eye. If concerned, seek medical advice.
- In case of contact with skin - Wash with plenty of water. If concerned, seek medical advice.

**5 FIRE-FIGHTING MEASURES**

- 5.1 Extinguishing media: Suitable - Will not burn unless dried out. Water jets, mist, foam, carbon dioxide or other dry agents, if contents dried out and burning.  
 Not suitable- None
- 5.2 If involved in a fire: If vials are broken and contents allowed to dry out, will burn and may give off noxious fumes (e.g. mainly carbon and nitrogen oxides and some chlorinated compounds). Wear breathing apparatus and protective clothing.

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6 ACCIDENTAL RELEASE MEASURES

Contain any spilled material immediately with paper towel or dry agent (sand, vermiculite, etc.) and vacuum or shovel into labelled containers for disposal (See Section 13).

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7 HANDLING AND STORAGE

- 7.1 Handling: Handle this product under conditions of good local exhaust ventilation or a laboratory Hood/fume cupboard to avoid exposure (e.g. breathing mist or fumes, swallowing, and eye and skin contact). If this is not possible, use personal protective equipment (Section 8).
- 7.2 Storage: Store in a cool place and replace lid after use.

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8 EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1 Respiratory: Not normally required for this product.
- 8.2 Hand: Chemical resistant gloves
- 8.3 Eye: At a minimum, safety glasses with side shields are required; goggles or eye/face shield may be needed if splashing may occur or handling significant quantities
- 8.4 Skin: At a minimum, a laboratory coat is needed; other protective overgarments (e.g., sleeve covers or tyvek garments) may be needed if splashing may occur or handling significant quantities

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9 PHYSICAL AND CHEMICAL PROPERTIES<sup>(1)</sup>

- 9.1 Appearance: Clear liquid      9.2 Odour: Not determined
- 9.3 pH: 8.4, approx.
- 9.4 Boiling Pt./range: >100°C.      9.5 Melting Pt./range: < 0°C.
- 9.6 Flash point: Not determined
- 9.7 Flammability: See 9.6      9.8 Autoflammability: See 9.6
- 9.9 Explosive properties: Not determined
- 9.10 Oxidising properties: Not determined      9.11 Vapour pressure: Not determined
- 9.12 Relative density: Not determined      9.13 Bulk density: See 9.12
- 9.14 Solubility:  
Water - Miscible in all proportions  
Fat (type) - Not determined  
Other solvents - Miscible in most polar solvents
- 9.15 Partition coefficient<sup>(2)</sup>: Log P<sub>o/w</sub> (Octanol/water) - Not determined
- 9.16 Other data: None relevant to safety
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10 STABILITY AND REACTIVITY

10.1 Conditions to avoid: None known.

10.2 Materials to avoid: Avoid mixing with oxidising agent and strong bases.

10.3 Hazardous decomposition products:

Mainly carbon and nitrogen oxides, and some chlorinated products may be released on burning or heating to decomposition.

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11 TOXICOLOGICAL INFORMATION

Acute effects<sup>(2,3)</sup>

This formulation has not been tested, but based on its components and the application of the EU "conventional method," it is not classified as "dangerous." However, it has not been fully tested, so precautions should be taken to avoid exposure.

Chronic effects<sup>(2,3)</sup>

No known chronic effects provided that precautions are taken to avoid acute effects described above.

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12 ECOLOGICAL INFORMATION

This formulation has not been tested. Therefore, avoid discharge to water systems.

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13 DISPOSAL CONSIDERATIONS

Users should acquaint themselves with local regulations.

Waste should not be considered as "hazardous waste". Under European Waste regulations, it is categorised as Catalogue Index No. 18 01 06 (18 = wastes from human or animal care and/or related research; 01 = wastes from natal care, diagnosis, treatment or prevention of disease in humans and 06 = chemicals containing dangerous substances).

Do not dispose of waste down the drain. Disposal may be carried out by collecting the waste and burning under controlled conditions at a licensed waste material processor; stack gases will need to be scrubbed.

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14 TRANSPORT INFORMATION

Proper Shipping Name: Not classified as dangerous for transport

UN No.: None Symbol: None

Hazard Class: None

ADR/RID Item No: None

IATA/DGR limits: None

IMDG/IMO Code: None

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15 REGULATORY INFORMATION

Components listed as "dangerous" in Annex I to Directive 67/548/EEC<sup>(2)</sup>

<u>Component or impurity</u>	<u>Annex I Number</u>
Aliphatic amine hydrochloride	Proprietary

Classified according to the Directives 67/548/EEC and 1999/45/EC, and their various amendments, and US hazard communication regulations (29 CFR 1910.1200) and labelled as below:-

SPECIMEN TRANSPORT MEDIUM 

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Warning symbol(s)	-	None
Warning words	-	None
Risk phrases	-	None
Safety Phrases	-	None

16 OTHER INFORMATION

<u>Occupational Exposure Levels</u>	<u>mg/m<sup>3</sup></u>		<u>Reference</u>
	<u>8h-TWA</u>	<u>Short-term</u>	
Sodium azide	0.1	0.3 (15-min)	EU-IOELV, UK US-ACGIH TLV; US OSHA PEL, Denmark, Norway Holland Sweden Finland Germany
	-	0.3 (15-min)	
	0.3 (ceiling)	-	
	0.3	0.3 (15-min)	
	0.27	0.81 (15-min)	
	0.2	-	

Inventories - All components are listed in TSCA and EINECS inventories

Intended uses - Laboratory use by experienced clinicians for *in vitro* diagnoses.

Revisions - The latest information changes are marked with | in the left margin

References - (1) In-house files.  
 (2) Annex I to Dangerous Substance Directive 67/548/EEC  
 (3) EU Directive 1999/45/EC

The format of this Safety Data Sheet conforms to the requirements of EC Directive 91/155/EEC and US ANSI/CMA guidelines.

Disclaimer - Although reasonable care has been taken in the preparation of this document to assess and summarise the hazard properties of the product, the user must satisfy himself that the information contained herein is pertinent to permit safe handling under his use conditions, since the supplier cannot foresee all conditions of use. The information contained herein is not intended as a product specification.

## DIGENE Corporation Signing Page

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