

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	Document No. MS-0502	Revision: 00
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编者 Originator: <i>Walter Wu</i>	日期 Date: <i>2016.02.04</i>	编制部门 Prepared Department: <i>RD</i>
审核人 Reviewed by: <i>Jason Lu</i>	日期 Date: <i>2016.02.04</i>	审核部门 Reviewed Department: <i>QA/RA</i>
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## SAFETY DATA SHEET

### HCG Test Strip/Device (Innovacon)

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

This document contains SDS for the following kit components.

HCG test strip/device

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

<b>1.1 Product identifier</b>	
Trade name	Innovacon HCG, Test device
Reference No.	FHC-101, FHC-111, FHC-201, FHC-A102, FHC-102, FHC-A202, FHC-202
<b>1.2 Relevant identified uses of the substance or mixture and uses advised against</b>	
Identified use(s)	In vitro diagnostic reagent. For professional use only.
<b>1.3 Details of the supplier of the safety data sheet</b>	
Company Identification	Innovacon, Inc. 9975 Summers Ridge Road San Diego, CA 92121, USA 1-858-805-4808 info@innovaconinc.com
Telephone	
E-Mail (competent person)	
<b>1.4 Emergency telephone number</b>	
Emergency Phone No.	ChemTel Inc. International access: + (0)1-813-248-0585 ChemTel Inc. Free phone (North America only): 1-(800)-255-3924

#### SECTION 2: HAZARDS IDENTIFICATION

<b>2.1 Classification of the substance or mixture</b>	
Regulation (EC) No. 1272/2008 (CLP)	Eye Irrit. 2
Hazard statement(s)	H319: Causes serious eye irritation.
Directive 67/548/EEC & Directive 1999/45/EC	Not classified as dangerous for supply/use.
OSHA Hazard Communication Standard 29 CFR 1910.1200 (HazCom 2012) / GHS	Eye Irrit. 2
Hazard statement(s)	Causes serious eye irritation.
<b>2.2 Label elements</b>	
	No measures required. The product is placed on the market in the form of an article, which contains insignificant quantities of hazardous chemicals that are not intended to be released from the device.
<b>2.3 Other hazards</b>	
	None anticipated.

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Mixtures

Description:

In vitro diagnostic reagent test device. Preparation. Laminated test strip consisting of solid support materials impregnated with dried chemical / biochemical reagents.

Dangerous components:

EC Classification No. 1272/2008 / GHS

Hazardous ingredient(s)	%W/W	EC No.	CAS No.	Classification code: Hazard statement(s)
Sodium carbonate	1 - 2	207-838-8	497-19-8	Eye Irrit. 2; H319
Triton X100*	1 - 2	-	9002-93-1	Acute Tox. 4; H302 Eye Dam. 1; H318 Aquatic Chronic 2; H411
Sodium azide**	< 0.1	247-852-1	26628-22-8	Acute Tox. 2; H300 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032

EC Classification No. 67/548/EEC

Hazardous ingredient(s)	%W/W	EC No.	CAS No.	EC Classification and Risk Phrases
Sodium carbonate	1 - 2	207-838-8	497-19-8	Xi; R36
Triton X100*	1 - 2	-	9002-93-1	Xn; R22-41-51/53
Sodium azide**	< 0.1	247-852-1	26628-22-8	T+, N; R28-32-50/53

\* candidate substance of very high concern (SVHC)

\*\* Substance with a community exposure limit

#### 3.2 Additional Information

For full text of R/H phrases see section 16.  
Each device is packaged in a foil pouch.

### SECTION 4: FIRST AID MEASURES



#### 4.1 Description of first aid measures

General information

Inhalation  
Skin Contact  
Eye Contact

Ingestion

#### 4.2 Most important symptoms and effects, both acute and delayed

#### 4.3 Indication of the immediate medical attention and special treatment needed

The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the test strip.  
Supply fresh air; consult doctor in case of complaint.  
Wash skin with soap and water.  
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention.  
Wash out mouth with water. Consult a doctor.  
None.

None.

### 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.

#### 5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released: Hazardous fumes, Carbon oxides (CO<sub>x</sub>), nitrogen oxides (NO<sub>x</sub>).

#### 5.3 Advice for fire-fighters

Use fire-extinguishing methods suitable to surrounding

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conditions.  
Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

- |     |   |  |
|-----|---|--|
| 6.1 | Personal precautions, protective equipment and emergency procedures | Refer to Section 8 for protective measures when handling the spillage. |
| 6.2 | Environmental precautions   | Avoid release to the environment.                                      |
| 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


- |     |  |   |
|-----|--|---|
| 7.1 | Precautions for safe handling                                | Specimens should be handled as potentially infectious materials. Refer to EU directive 2000/54EC or US regulation 29 CFR 1910.1030 for information on handling biohazardous materials.<br>Avoid contact with the eyes, skin and mucous membranes. Keep out of reach of children.<br>Wash hands before breaks and after work.<br>Clean work areas with hypochlorite or other disinfecting agent. |
| 7.2 | Conditions for safe storage, including any incompatibilities | Store in the original container at 2 to 30°C.   |
| 7.3 | Specific end use(s)  | Use as per instructions for use.  |

### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

- |       |                              |                              |
|-------|------------------------------|------------------------------|
| 8.1   | Control parameters           |                              |
| 8.1.1 | Occupational Exposure Limits | EU IOELV / UK WEL / IrI OELV |

SUBSTANCE.	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m <sup>3</sup> )	STEL (ppm)	STEL (mg/m <sup>3</sup> )	Note:
Sodium Azide	26628-22-8		0.1		0.3	Sk

Sk - Can be absorbed through skin.

- |       |   |  |
|-------|---|--|
| 8.2   | Exposure controls   |  |
| 8.2.1 | Appropriate engineering controls  | Not relevant for this material.  |
| 8.2.2 | Personal protection equipment   | Safety glasses recommended. (EN166)  |
|       | Eye/face protection   |  |
|       | Hand protection   | Disposable gloves. (EN374).  |
|       |  |  |
|       | 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

- |     |   |  |
|-----|---|--|
| 9.1 | Information on basic physical and chemical properties |  |
|     | Appearance  | Laminated test strip, which may be housed in a plastic |

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Colour	holder.
Odour	Variable depending on product.
Odour Threshold (ppm)	No odour.
pH (Value)	Not applicable.
Melting Point (°C) / Freezing Point (°C)	Not determined.
Boiling point/boiling range (°C):	Not determined.
Flash Point (°C)	Not applicable.
Evaporation rate (BA = 1)	Not applicable.
Flammability (solid, gas)	Not determined.
Explosive limit ranges	Not applicable.
Vapour Pressure (mm Hg)	Not applicable.
Vapour Density (Air=1)	Not applicable.
Density (g/ml)	Not applicable.
Solubility (Water)	Not determined.
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	Contact with acids may liberate trace amounts of toxic gas (hydrazoic acid). Hazardous polymerisation will not occur.
10.4 Conditions to avoid	None.
10.5 Incompatible materials	None.
10.6 Hazardous Decomposition Product(s)	None known.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

#### 11.1.1 Mixtures

Acute toxicity	Based upon the available data, the classification criteria are not met.
Irritation	Causes serious eye irritation.
Corrosivity	Based upon the available data, the classification criteria are not met.
Sensitisation	Based upon the available data, the classification criteria are not met.
Repeated dose toxicity	Based upon the available data, the classification criteria are not met.
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Mutagenicity	Based upon the available data, the classification criteria are not met.
Toxicity for reproduction	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.

11.2 Other information	Not applicable
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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	None anticipated.
12.4 Mobility in soil	The product is predicted to have low mobility in soil.
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:	Used devices and other contaminated materials should be disposed of as potentially biohazardous waste. Disposal should be in accordance with local, state or national legislation. 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 03.
Packaging:	Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product. Non-contaminated 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):	Sodium azide (trace).

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Section 313 (specific toxic chemical listings): Sodium azide (trace).

15.2 Chemical Safety Assessment Not applicable.

## SECTION 16: OTHER INFORMATION

### LEGEND

STOT	Specific Target Organ Toxicity
STEL	Short Term Exposure Limit
LTEL	Long Term Exposure limit
TWA	Time Weighted Average

### Classification code:

Acute Tox. 4	Acute toxicity; Category 4
Acute Tox. 2	Acute toxicity; Category 2
Eye Dam. 1	Eye damage; Category 1
Eye Irrit. 2	Eye Irritation; Category 2
Aquatic Acute 1	Hazardous to the aquatic environment Acute: Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment Chronic: Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment Chronic: Category 2
Xi	Irritant
Xn	Harmful.
T+	Very toxic.
N	Dangerous for the environment.

### Hazard statement(s)

H300: Fatal if swallowed.  
H302: Harmful if swallowed.  
H318: Causes serious eye damage.  
H319: Causes serious eye irritation.  
H400: Very toxic to aquatic life.  
H410: Very toxic to aquatic life with long lasting effects.  
H411: Toxic to aquatic life with long lasting effects.  
EUH032: Contact with acids liberates very toxic gas.

### Risk Phrases

R22: Harmful if swallowed.  
R28: Very toxic if swallowed.  
R32: Contact with acids liberates very toxic gas.  
R36: Irritating to eyes.  
R41: Risk of serious damage to eyes.  
R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
R51/53: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

### References:

Raw material safety data sheets.

### Additional Information

Reason for update: Update in accordance with Regulation (EU) No 453/2010.  
Regulation (EC) No. 1272/2008 (CLP) & GHS  
Changes to all sections.

Supersedes: Version: 2

Prepared by: Dr. J. J. Tobin, ChemHaz Solutions, Email: info@chemhazsolutions.com

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## 文件更改概要

Document Change Summary

修改后版本和 修订号 Updated Version and Revision	生效日期 Effective Date	更改概述 Summary of Changes	审批单 编号 DAF Ref
Ver.A,Rev.00	2016.02.05	New document	DAF-160067