

2018402A06H

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0504 Agile 文件编号: MS-0504
文件名称 Document Name: Safety Data Sheet MONO Positive Controls (Innovacon)		
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发放号 Distribution No:

## SAFETY DATA SHEET

### MONO Positive control (Innovacon)

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

This document contains SDS for the following kit components.

Positive control

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

**1.1 Product identifier**

Trade name

Mono Positive Control

Reference No.

IMO-402

**1.2 Relevant identified uses of the substance or mixture and uses advised against**

Identified use(s)

In vitro diagnostic reagent. For professional use only.

**1.3 Details of the supplier of the safety data sheet**

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)

**1.4 Emergency telephone number**

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

**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 anticipated.

#### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

**3.1 Mixtures**

Description:

In vitro diagnostic reagent. Aqueous solution.

Dangerous components:

EC Classification No. 1272/2008

Hazardous ingredient(s)	CAS No.	EC No.	REACH Registration No.	Classification code: Hazard statement(s)	%W/W
Sodium azide*	26628-22-8	247-852-1	Not available	Acute Tox. 2; H300	< 0.1

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				Acute Tox. 1; H310 STOT RE 2; H373 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032	
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\* Substance with a community exposure limit.

### 3.2 Additional Information

For full text of H phrases see section 16.

## SECTION 4: FIRST AID MEASURES



### 4.1 Description of first aid measures

Inhalation

Skin Contact

Eye Contact

Ingestion

Supply fresh air; consult doctor in case of complaint.

Wash skin with soap and water. Remove contaminated clothing and wash clothing before reuse.

Rinse cautiously with water for several minutes. Consult a doctor in case of complaint.

Wash out mouth with water. Consult a doctor.

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

None.

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

None.

## SECTION 5: FIRE-FIGHTING MEASURES

### 5.1 Extinguishing media

Suitable Extinguishing Media

CO2, 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 (COx), nitrogen oxides (NOx), phosphorous oxides (PxOy).

### 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

### 6.1 Personal precautions, protective equipment and emergency procedures

Refer to Section 8 for protective measures when handling the spillage.

### 6.2 Environmental precautions

Do not allow the undiluted product to enter sewers/surface or ground water.

### 6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (paper towelling, sand, diatomite, acid binders, universal binders, sawdust). Dispose of contaminated material as waste according to Section 13. Rinse off area with water.

### 6.4 Reference to other sections

8, 13

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Avoid contact with the eyes, skin and mucous membranes. Keep out of reach of children. Wash hands before breaks and after work.

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- 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 EH40 / ACGIH TLV

SUBSTANCE.	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m³)	STEL (ppm)	STEL (mg/m³)	Note:
Sodium Azide	26628-22-8		0.1		0.3	Sk
				0.11 (HN <sub>3</sub> )	0.29 (NaN <sub>3</sub> )	ACGIH TLV

Sk - Can be absorbed through skin.

- 8.2 Exposure controls
- 8.2.1 Appropriate engineering controls
- 8.2.2 Personal protection equipment

Not relevant for this material.

Eye/face protection

Safety glasses recommended. (EN166)

Hand protection

Disposable gloves. (EN374).



Material of gloves:  
Penetration time of glove material:

Latex / natural rubber, Nitrile rubber.  
Gloves resistance is not critical when the product is handled according to the instructions for use.

Body protection  
Respiratory protection

Laboratory coat.  
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  
Colour  
Odour  
Odour Threshold (ppm)  
pH (Value)  
Melting Point (°C) / Freezing Point (°C)  
Boiling point/boiling range (°C):  
Flash Point (°C)  
Evaporation rate (BA = 1)  
Flammability (solid, gas)  
Explosive limit ranges  
Vapour Pressure (Pascal)  
Vapour Density (Air=1)  
Density (g/ml)  
Solubility (Water)  
Solubility (Other)  
Partition Coefficient (n-Octanol/water)  
Auto Ignition Temperature (°C)  
Decomposition Temperature (°C)  
Viscosity (mPa.s)  
Explosive properties  
Oxidising properties

Clear liquid.  
Colourless.  
Odourless  
Not determined.  
Not determined.  
Similar to water, approximately 0°C.  
Similar to water, approximately 100°C.  
Not applicable.  
Not determined.  
Not applicable.  
Not applicable.  
Similar to water, approximately 23 hPa.  
Not determined.  
1.01  
Soluble.  
Not determined.  
Not determined.  
Not determined.  
Not determined.  
Not determined.  
Not explosive.  
Not oxidising  
Not available.

- 9.2 Other information

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## 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	Preparation contains sodium azide, which may react with lead to form explosive compounds. Contact with acids may liberate trace amounts of toxic gas (hydrazoic acid). Hazardous polymerisation will not occur.
10.4 Conditions to avoid	None known.
10.5 Incompatible materials	Concentrated acids, heavy metals, metallic salts.
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. ATE > 2,000 mg/kg
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.
<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.

### 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 product is biodegradable.
12.3 Bioaccumulative potential	None anticipated.
12.4 Mobility in soil	The product is predicted to have high 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

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**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.

To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent.

**European waste catalogue:**

18 01 07.

**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 Water hazard class: (Germany): -
<b>Carcinogen listings</b> IARC: NTP: ACGIH: OSHA: EPA: <b>Californian Proposition 65</b> Chemicals known to cause cancer: Chemicals known to cause reproductive toxicity: <b>SARA</b> Section 355 (extremely hazardous substances): Section 313 (specific toxic chemical listings):	None of the ingredients is listed. None of the ingredients is listed. None of the ingredients is listed. None of the ingredients is listed. None of the ingredients is listed. None of the ingredients is listed. None of the ingredients is listed. None of the ingredients is listed. Sodium azide. Sodium azide.
15.2 Chemical Safety Assessment	Not applicable.

**SECTION 16: OTHER INFORMATION****LEGEND**

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STOT	Specific Target Organ Toxicity
STEL	Short Term Exposure Limit
LTEL	Long Term Exposure limit
TWA	Time Weighted Average
TLV	Threshold Limit Value
ATE	Acute toxicity estimate

**Classification code:**

Acute Tox. 1	Acute toxicity, Category 1
Acute Tox. 2	Acute toxicity: Category 2
STOT RE 2	Specific Target Organ Toxicity, repeat exposure, Category 2
Aquatic Acute 1	Acute Aquatic toxicity: Category 1
Aquatic Chronic 1	Chronic Aquatic toxicity: Category 1

**Hazard statement(s)**

H300: Fatal if swallowed.  
H310: Fatal in contact with skin.  
H373: May cause damage to organs through prolonged or repeated exposure.  
H400: Very toxic to aquatic life.  
H410: Very toxic to aquatic life with long lasting effects.  
EUH032: Contact with acids liberates very toxic gas.

**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

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To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

2018年02月06日

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文件更改概要

Document Change Summary

审批单 编号 CO/DAF	更改概述 Summary of Changes
CO-10014056	Change the format of page header for document.