

SAFETY DATA SHEET (SDS)

407 New Sanford Road La Vergne, TN 37086

IHP-402 Negative Control

according to Regulation (EC) No. 453/2010

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture

Product name : Pro Advantage H Pylori Test IHP-402 Negative Control

Product group : Blend

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

1.2.1. Relevant identified uses

Main use category : Professional use

Industrial/Professional use spec : For professional use only

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

NDC, Inc.

407 New Sanford Road LaVergne, TN 37086 615-366-3230

1.4. Emergency telephone number

Emergency number : For Medical Test Device / Test Device Kit information and technical assistance, please

contact the Technical Services Department at 1-888-246-7483 (option 2).

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



GHS07

Signal word (CLP) : Warning

Hazard statements (CLP) : H302 - Harmful if swallowed

H412 - Harmful to aquatic life with long lasting effects

Precautionary statements (CLP) : P264 - Wash hands thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P273 - Avoid release to the environment

P330 - Rinse mouth

P501 - Dispose of contents/container: Dispose in a safe manner in accordance with

local/national regulations

EUH phrases : EUH401 - To avoid risks to human health and the environment, comply with the instructions for

use

2.3. Other hazards

Adverse physicochemical, human health and

environmental effects

 None under normal conditions. To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

Other hazards not contributing to the

classification

: None under normal conditions. This product contains material of human and animal origin.

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SECTION 3: Composition/information on ingredients

Substance

Not applicable

3.2. **Mixture**

Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Tris (hydroxymethyl) aminomethane	(CAS No) 77-86-1 (EC no) 201-064-4	6.05	Xi; R36/37/38	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
Sodium Azide	(CAS No) 26628-22-8 (EC no) 247-852-1 (EC index no) 011-004-00-7	0.09	T+; R28 R32 N; R50/53	Acute Tox. 2 (Oral), H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of R- and H-phrases: see section 16

SECTION 4: First aid measures

Description of first aid measures

: Under normal conditions of use, no adverse effects to health have been observed. First-aid measures general

First-aid measures after inhalation Not expected to present a significant inhalation hazard under anticipated conditions of normal

First-aid measures after skin contact : Gently wash with plenty of soap and water.

First-aid measures after eye contact Not expected to present a significant eye contact hazard under anticipated conditions of normal

: Not expected to present a significant ingestion hazard under anticipated conditions of normal First-aid measures after ingestion

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

Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/injuries after inhalation : None under normal use. Symptoms/injuries after skin contact : None under normal use. Symptoms/injuries after eye contact None under normal use. Symptoms/injuries after ingestion : None under normal use. Symptoms/injuries upon intravenous : None under normal use.

administration

Chronic symptoms

: None under normal use.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

Extinguishing media

Suitable extinguishing media : Water spray. Foam.

Unsuitable extinguishing media : No unsuitable extinguishing media known.

Special hazards arising from the substance or mixture 5.2.

Fire hazard : No direct or indirect fire hazard identified.

Explosion hazard : No direct explosion hazard. Reactivity in case of fire : None under normal conditions.

Hazardous decomposition products in case of

5.3. **Advice for firefighters**

Precautionary measures fire : Evacuate area. Stop leak if safe to do so. : No specific fire-fighting instructions required. Firefighting instructions

: fume.

Protection during firefighting : Do not attempt to take action without suitable protective equipment.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

General measures : No open flames. No smoking. Absorb spillage to prevent material damage.

For non-emergency personnel

Protective equipment : Protective clothing as deemed necessary.

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Emergency procedures : Avoid contact with skin, eyes and clothing. Evacuate unnecessary personnel. Keep containers

closed. No open flames, no sparks, and no smoking.

Measures in case of dust release : No effects known.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment.

Emergency procedures : Contain any material as necessary.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Collect spillage and/or debris.

Methods for cleaning up : Carefully collect the spill/leftovers.

6.4. Reference to other sections

For further information refer to section 13. For further information refer to section 8: "Exposure controls/personal protection".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : No known hazards/None known.

Precautions for safe handling : Avoid contact during pregnancy/while nursing. Avoid contact with skin, eyes and clothing. Do

not eat, drink or smoke when using this product. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Keep out of reach of children. No open flames. No smoking. Observe normal hygiene standards. Wear

personal protective equipment.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the

product.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Comply with applicable regulations.

Storage conditions : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No

smoking. Keep container closed when not in use. Keep container tightly closed. Keep only in

original container. Store as directed in product literature. Store in original container.

Incompatible products : None known.

Incompatible materials : Away from heat sources.

Heat and ignition sources : No direct or indirect fire or ignition sources identified.

Prohibitions on mixed storage : None known.

Storage area : Keep container as directed in product literature.

Special rules on packaging : Keep only in original container. Proper handling and disposal methods should be established

by the laboratory in accordance with local, state, federal and national regulations.

Packaging materials : No data available.

7.3. Specific end use(s)

None known.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Sodium Azide (26628-22-8)		
EU	IOELV TWA (mg/m³)	0.1 mg/m³
EU	IOELV STEL (mg/m³)	0.3 mg/m ³
Belgium	Limit value (mg/m³)	0.1 mg/m³
Belgium	Short time value (mg/m³)	mg/m³
France	VME (mg/m³)	Azide de sodium,0.1 mg/m³; France; Time-weighted average exposure limit 8 h; VRC: Valeur réglementaire contraignante
France	VLE (mg/m³)	Azide de sodium,0.3 mg/m³; France; Short time value; VRC: Valeur réglementaire contraignante
Netherlands	Grenswaarde TGG 8H (mg/m³)	Natriumazide,0.1 mg/m³; Netherlands; Time-weighted average exposure limit 8 h; Public occupational exposure limit value
Netherlands	Grenswaarde TGG 15MIN (mg/m³)	Natriumazide,0.3 mg/m³; Netherlands; Short time value; Public occupational exposure limit value
United Kingdom	WEL TWA (mg/m³)	0.1 mg/m³
United Kingdom	WEL STEL (mg/m³)	0.3 mg/m ³
USA - ACGIH	ACGIH Ceiling (mg/m³)	0.29 mg/m³

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Sodium Azide (26628-22-8)		
USA - ACGIH	ACGIH Ceiling (ppm)	0.11 ppm

8.2. Exposure controls

Appropriate engineering controls : Wear recommended personal protective equipment.

Personal protective equipment : Avoid all unnecessary exposure. Gloves. In case of splash hazard: safety glasses. Protective







Thermal hazard protection : Not applicable.

Environmental exposure controls : Avoid release to the environment.

Consumer exposure controls : Avoid contact during pregnancy/while nursing.

Other information : Do not eat, drink or smoke when using this product.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Colour : No data available : No data available Odour Odour threshold : No data available : No data available Relative evaporation rate (butylacetate=1) : No data available : No data available Melting point Freezing point : No data available Boiling point : No data available No data available Flash point : No data available Auto-ignition temperature Decomposition temperature : No data available : No data available Flammability (solid, gas) Vapour pressure No data available : No data available Relative vapour density at 20 °C Relative density : No data available Solubility : No data available Log Pow No data available : No data available Viscosity, kinematic : No data available Viscosity, dynamic

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Explosive properties

Oxidising properties

Explosive limits

The product is non-reactive under normal conditions of use, storage and transport.

: No data available

: No data available

: No data available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

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10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Tris (hydroxymethyl) aminomethane (77-86	5-1)
LD50 oral rat	5900 mg/kg (Rat)
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Potential adverse human health effects and symptoms	: No data available.

SECTION 12: Ecological information

12.1. Toxicity

Other information

Sodium Azide (26628-22-8)		
LC50 fish 1	0.8 mg/l 96 h; Salmo gairdneri (Oncorhynchus mykiss)	
LC50 other aquatic organisms 1	1 (1 - 10) mg/l (96 h)	
EC50 Daphnia 1	4.2 mg/l (48 h; Daphnia pulex)	
EC50 other aquatic organisms 1	5 (5 - 14) mg/l (Protozoa; TOXICITY TEST)	
LC50 fish 2	0.7 mg/l (96 h; Lepomis macrochirus)	
TLM fish 1	1.5 ppm (24 h; Lepomis macrochirus)	
Threshold limit other aquatic organisms 1	1 - 10,96 h	

: Product is not listed as a carcinogen by ACGIH, IARC, NIOSH, NTP, OSHA, or Prop 65.

12.2. Persistence and degradability

Sodium Azide (26628-22-8)		
Persistence and degradability	Biodegradability: not applicable.	
Biochemical oxygen demand (BOD)	Not applicable	
Chemical oxygen demand (COD)	Not applicable	
ThOD	Not applicable	
BOD (% of ThOD)	Not applicable	
Tris (hydroxymethyl) aminomethane (77-86-1)		

Persistence and degradability Biodegradability in water: no data available.

12.3. Bioaccumulative potential

Sodium Azide (26628-22-8)		
Bioaccumulative potential not bioaccumulable.		
Tris (hydroxymethyl) aminomethane (77-86-1)		
Log Pow	-1.56	
Bioaccumulative potential	Bioaccumulation: not applicable.	

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

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12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Disposal must be done according to official regulations.

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

Sewage disposal recommendations : Disposal must be done according to official regulations.

Waste disposal recommendations : Avoid release to the environment. Dispose in a safe manner in accordance with local/national

regulations. Used Alere Medical Test Device / Test Device Kits should be decontaminated and disposed of using an autoclave or by incineration as "other waste" - containing biological material. Biological waste material must be disposed of in accordance with your facility's biological safety program that is consistent with National, federal, state, and local regulations. To ensure compliance with anti-pollution and other laws of the country concerned, we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Unused Alere Controls should be disposed of in accordance with your

facility's solid waste disposal policies.

Additional information : Clean up even minor leaks or spills if possible without unecessary risk.

Ecology - waste materials : Avoid release to the environment.

European List of Waste (LoW) code : 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to

prevent infection

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable
Packing group (ADN) : Not applicable
Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No Marine pollutant : No

Other information : No supplementary information available

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Special precautions for user 14.6.

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Inland waterway transport

Not subject to ADN : No

- Rail transport

Carriage prohibited (RID) : No

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. **EU-Regulations**

Contains no substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. **National regulations**

Germany

VwVwS Annex reference : Water hazard class (WGK) 2, hazard to waters (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act - 12.BlmSchV

: Is not subject of the 12. BlmSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting : None of the components are listed

giftige stoffen - Borstvoeding NIET-limitatieve lijst van voor de voortplanting : None of the components are listed

giftige stoffen - Vruchtbaarheid

NIET-limitatieve lijst van voor de voortplanting

giftige stoffen - Ontwikkeling

: None of the components are listed

Chemical safety assessment

Not listed under California Prop 65

SECTION 16: Other information

Full text of R-, H- and EUH-phrases:

Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2		
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1		
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1		
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2		
Skin Irrit. 2	Skin corrosion/irritation, Category 2		
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation		
H300	Fatal if swallowed		
H315	Causes skin irritation		
H319	Causes serious eye irritation		
H335	May cause respiratory irritation		
H400	Very toxic to aquatic life		
H410	Very toxic to aquatic life with long lasting effects		
EUH401	To avoid risks to human health and the environment, comply with the instructions for use		

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R28	Very toxic if swallowed
R32	Contact with acids liberates very toxic gas
R36/37/38	Irritating to eyes, respiratory system and skin
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
N	Dangerous for the environment
T+	Very toxic
Xi	Irritant

SDS EU (REACH Annex II)

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture

Product name : Pro Advantage H. Pylori Test IHP-402 Positive Control

Product group : Blend

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

1.2.1. Relevant identified uses

Main use category : Professional use

Industrial/Professional use spec : For professional use only

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

NDC, Inc

407 New Sanford Road LaVergne, TN 37086 615-366-3230

1.4. Emergency telephone number

Emergency number : For Medical Test Device / Test Device Kit information and technical assistance, please

contact the Technical Services Department at 1-888-246-7483 (option 2).

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) : Warning

Hazard statements (CLP) : H302 - Harmful if swallowed

H412 - Harmful to aquatic life with long lasting effects

Precautionary statements (CLP) : P264 - Wash hands thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P273 - Avoid release to the environment

P330 - Rinse mouth

 $\ensuremath{\mathsf{P501}}$ - Dispose of contents/container: Dispose in a safe manner in accordance with

local/national regulations

EUH phrases : EUH401 - To avoid risks to human health and the environment, comply with the instructions for

use

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

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Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sodium Azide	(CAS No) 26628-22-8 (EC no) 247-852-1 (EC index no) 011-004-00-7	0.08995	T+; R28 R32 N; R50/53	Acute Tox. 2 (Oral), H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of R- and H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Under normal conditions of use, no adverse effects to health have been observed.

First-aid measures after inhalation : Not expected to present a significant inhalation hazard under anticipated conditions of normal

use.

First-aid measures after skin contact : Gently wash with plenty of soap and water.

First-aid measures after eye contact : Not expected to present a significant eye contact hazard under anticipated conditions of normal

use.

First-aid measures after ingestion : Not expected to present a significant ingestion hazard under anticipated conditions of normal

use.

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

Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/injuries after inhalation : None under normal use. Symptoms/injuries after skin contact : None under normal use. Symptoms/injuries after eye contact : None under normal use. Symptoms/injuries after ingestion : None under normal use. Symptoms/injuries upon intravenous : None under normal use.

administration
Chronic symptoms

: None under normal use.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Foam.

Unsuitable extinguishing media : No unsuitable extinguishing media known.

5.2. Special hazards arising from the substance or mixture

Fire hazard : No direct or indirect fire hazard identified.

Explosion hazard : No direct explosion hazard.

Reactivity in case of fire : None under normal conditions.

Hazardous decomposition products in case of

fire

: fume.

5.3. Advice for firefighters

Precautionary measures fire : Evacuate area. Stop leak if safe to do so. Firefighting instructions : No specific fire-fighting instructions required.

Protection during firefighting : Do not attempt to take action without suitable protective equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : No open flames. No smoking. Absorb spillage to prevent material damage.

6.1.1. For non-emergency personnel

Protective equipment : Protective clothing as deemed necessary.

Emergency procedures : Avoid contact with skin, eyes and clothing. Evacuate unnecessary personnel. Keep containers

closed. No open flames, no sparks, and no smoking.

Measures in case of dust release : No effects known.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment.

Emergency procedures : Contain any material as necessary.

6.2. Environmental precautions

Avoid release to the environment.

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6.3. Methods and material for containment and cleaning up

For containment : Collect spillage and/or debris.

Methods for cleaning up : Carefully collect the spill/leftovers.

6.4. Reference to other sections

For further information refer to section 13. For further information refer to section 8: "Exposure controls/personal protection".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed

: No known hazards/None known.

Precautions for safe handling

Avoid contact with skin, eyes and clothing. Do not eat, drink or smoke when using this product. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Keep out of reach of children. Observe normal hygiene standards. Wear personal protective equipment.

Hygiene measures

: Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures

: Comply with applicable regulations. Does not require any specific or particular technical

measures

None known.

Storage conditions

: Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container closed when not in use. Keep only in original container. Store in original container. Store as directed in product literature.

Incompatible products

Incompatible materials : Away from heat sources.

Heat and ignition sources : No direct or indirect fire or ignition sources identified.

Prohibitions on mixed storage : None known.

Storage area : Keep container as directed in product literature.

Special rules on packaging : Keep only in original container. Proper handling and disposal methods should be established

by the laboratory in accordance with local, state, federal and national regulations.

Packaging materials : No data available.

7.3. Specific end use(s)

None known.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Sodium Azide (26628-22-8)		
EU	IOELV TWA (mg/m³)	0.1 mg/m³
EU	IOELV STEL (mg/m³)	0.3 mg/m³
Belgium	Limit value (mg/m³)	0.1 mg/m³
Belgium	Short time value (mg/m³)	mg/m³
France	VME (mg/m³)	Azide de sodium,0.1 mg/m³; France; Time-weighted average exposure limit 8 h; VRC: Valeur réglementaire contraignante
France	VLE (mg/m³)	Azide de sodium,0.3 mg/m³; France; Short time value; VRC: Valeur réglementaire contraignante
Netherlands	Grenswaarde TGG 8H (mg/m³)	Natriumazide,0.1 mg/m³; Netherlands; Time-weighted average exposure limit 8 h; Public occupational exposure limit value
Netherlands	Grenswaarde TGG 15MIN (mg/m³)	Natriumazide,0.3 mg/m³; Netherlands; Short time value; Public occupational exposure limit value
United Kingdom	WEL TWA (mg/m³)	0.1 mg/m³
United Kingdom	WEL STEL (mg/m³)	0.3 mg/m³
USA - ACGIH	ACGIH Ceiling (mg/m³)	0.29 mg/m ³
USA - ACGIH	ACGIH Ceiling (ppm)	0.11 ppm

8.2. Exposure controls

Appropriate engineering controls

: Wear recommended personal protective equipment.

Personal protective equipment

: Avoid all unnecessary exposure. Gloves. In case of splash hazard: safety glasses. Protective clothing.

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Safety Data Sheet

according to Regulation (EC) No. 453/2010







Thermal hazard protection : Not applicable.

Environmental exposure controls : Avoid release to the environment.

Consumer exposure controls : Avoid contact during pregnancy/while nursing.

Other information : Do not eat, drink or smoke when using this product.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Colour : No data available : No data available Odour Odour threshold No data available No data available pΗ Relative evaporation rate (butylacetate=1) : No data available : No data available Melting point Freezing point No data available : No data available Boiling point : No data available Flash point : No data available Auto-ignition temperature Decomposition temperature No data available : No data available Flammability (solid, gas) : No data available Vapour pressure Relative vapour density at 20 °C : No data available Relative density No data available Solubility : No data available : No data available Log Pow No data available Viscosity, kinematic Viscosity, dynamic No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Explosive properties

Oxidising properties

Explosive limits

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

: No data available: No data available

: No data available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

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according to Regulation (EC) No. 453/2010

: Not classified Skin corrosion/irritation Serious eye damage/irritation : Not classified Respiratory or skin sensitisation Not classified Germ cell mutagenicity Not classified Carcinogenicity : Not classified Reproductive toxicity : Not classified Specific target organ toxicity (single exposure) : Not classified Specific target organ toxicity (repeated : Not classified exposure)

: Not classified Aspiration hazard Potential adverse human health effects and

symptoms

Other information

: No data available.

: Product is not listed as a carcinogen by ACGIH, IARC, NIOSH, NTP, OSHA, or Prop 65.

SECTION 12: Ecological information

12.1. **Toxicity**

Sodium Azide (26628-22-8)			
LC50 fish 1	0.8 mg/l 96 h; Salmo gairdneri (Oncorhynchus mykiss)		
LC50 other aquatic organisms 1	1 (1 - 10) mg/l (96 h)		
EC50 Daphnia 1	4.2 mg/l (48 h; Daphnia pulex)		
EC50 other aquatic organisms 1	5 (5 - 14) mg/l (Protozoa; TOXICITY TEST)		
LC50 fish 2	0.7 mg/l (96 h; Lepomis macrochirus)		
TLM fish 1	1.5 ppm (24 h; Lepomis macrochirus)		
Threshold limit other aquatic organisms 1	1 - 10,96 h		

12.2. Persistence and degradability

Sodium Azide (26628-22-8)	
Persistence and degradability	Biodegradability: not applicable.
Biochemical oxygen demand (BOD)	Not applicable
Chemical oxygen demand (COD)	Not applicable
ThOD	Not applicable
BOD (% of ThOD)	Not applicable

12.3. **Bioaccumulative potential**

Sodium Azide (26628-22-8)	
Bioaccumulative potential	not bioaccumulable.

Mobility in soil

No additional information available

Results of PBT and vPvB assessment

No additional information available

Other adverse effects

No additional information available

SECTION 13: Disposal considerations

Waste treatment methods

: Disposal must be done according to official regulations. Regional legislation (waste)

: Dispose of contents/container in accordance with licensed collector's sorting instructions. Waste treatment methods

Sewage disposal recommendations : Disposal must be done according to official regulations.

: Avoid release to the environment. Used Innovacon Medical Test Device / Test Device Kits Waste disposal recommendations should be decontaminated and disposed of using an autoclave or by incineration as "other

waste" - containing biological material. Biological waste material must be disposed of in accordance with your facility's biological safety program that is consistent with National, federal, state, and local regulations. To ensure compliance with anti-pollution and other laws of the country concerned, we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Unused Innovacon Controls should be disposed of in accordance with your facility's solid waste disposal policies.

Additional information : Clean up even minor leaks or spills if possible without unecessary risk.

Ecology - waste materials : Avoid release to the environment.

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European List of Waste (LoW) code

: 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable
Packing group (ADN) : Not applicable
Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Inland waterway transport

Not subject to ADN : No

- Rail transport

Carriage prohibited (RID) : No

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

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SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture 15.1.

15.1.1. **EU-Regulations**

Contains no substances with Annex XVII restrictions Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

National regulations 15.1.2.

Germany

VwVwS Annex reference : Water hazard class (WGK) 1, low hazard to waters (Classification according to VwVwS, Annex

4)

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV

: Is not subject of the 12. BlmSchV (Hazardous Incident Ordinance)

Netherlands

: SERUM ALBUMIN is listed SZW-lijst van kankerverwekkende stoffen SZW-lijst van mutagene stoffen : SERUM ALBUMIN is listed

NIET-limitatieve lijst van voor de voortplanting

giftige stoffen - Borstvoeding

NIET-limitatieve lijst van voor de voortplanting

giftige stoffen - Vruchtbaarheid

NIET-limitatieve lijst van voor de voortplanting

giftige stoffen - Ontwikkeling

: None of the components are listed : None of the components are listed

: None of the components are listed

15.2. **Chemical safety assessment**

Not listed under California Prop 65

SECTION 16: Other information

Full text of R-, H- and EUH-phrases:

Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
H300	Fatal if swallowed
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
EUH401	To avoid risks to human health and the environment, comply with the instructions for use
R28	Very toxic if swallowed
R32	Contact with acids liberates very toxic gas
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
N	Dangerous for the environment
T+	Very toxic

SDS EU (REACH Annex II)

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