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

1.1. Product identifier

Trade name: QuikRead go Strep A
Catalogue number: 135883

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

The uses of the chemical: For in vitro diagnostic use

1.3. Details of the supplier of the safety data sheet:

Manufacturer/importer: Orion Diagnostica Oy
Street address: Koivu-Mankkaan tie 6 B
Post-office box: P.O. Box 83
Postcode: 02101 Espoo, Finland
Telephone number: +358 10 4261
Telefax: +35810 426 2794
E-mail address: product.support@oriondiagnostica.fi
VAT Reg. No: FI18552161

1.4. Emergency telephone number

Orion Diagnostica Oy +358 10 426 3344

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture


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Name of the Component	Classification according to regulation EC 1272/2008	H Statements
Strep A Reagent Caps	Aquatic Chronic 3 ;H412	Harmful to aquatic life with long lasting effects.
Extraction Reagent 1	Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008. ;	
Extraction Reagent 2	Acute Tox. 4 ;H302	Harmful if swallowed.
Buffer in prefilled cuvettes	Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008. ;	
Positive Control	Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008. ;	
Negative control	Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008. ;	

2.2. Label elements

Name of the Component	Hazard Pictograms	Signal word	H Statements	P Statements
Strep A Reagent Caps		Not applicable	H412 Harmful to aquatic life with long lasting effects.	P273 Avoid release to the environment. P501 Dispose of contents according to national and local law.

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Extraction Reagent 1		Not applicable	NA Not applicable	NA Not applicable
Extraction Reagent 2		Warning	H302 Harmful if swallowed.	P270 Do not eat, drink or smoke when using this product. P301+P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. P501 Dispose of contents according to national and local law.
Buffer in prefilled cuvettes		Not applicable	NA Not applicable	NA Not applicable
Positive Control		Not applicable	NA Not applicable	NA Not applicable
Negative control		Not applicable	NA Not applicable	NA Not applicable

2.3. Other hazards

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Name of the ingredient	CAS-number:	EC-number	Reach registration number:	Concentration/ Limit	Classification according to regulation EC 1272/2008

Strep A Reagent Caps

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Sodium azide	26628-22-8		NA	<1,0%	Acute Tox. 2, Aquatic Acute 1, Aquatic Chronic 1 ;H300 EUH032 H400 H410
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Extraction Reagent 1

Acetic acid	64-19-7	200-580-7	01-2119475328-30	<7,5%	Flam. Liq. 3, Skin Corr. 1A ;H226 H314
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Extraction Reagent 2

Sodium nitrite	7632-00-0		NA	<25%	Ox. Sol. 3, Acute Tox. 3, Aquatic Acute 1 ;H272 H301 H400
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Buffer

Sodium azide	26628-22-8		NA	<0,1%	Acute Tox. 2, Aquatic Acute 1, Aquatic Chronic 1 ;H300 EUH032 H400 H410
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Positive Control

Sodium azide	26628-22-8		NA	<0,1%	Acute Tox. 2, Aquatic Acute 1, Aquatic Chronic 1 ;H300 EUH032 H400 H410
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Negative Control

Sodium azide	26628-22-8		NA	<0,1%	Acute Tox. 2, Aquatic Acute 1, Aquatic Chronic 1 ;H300
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					EUH032 H400 H410
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Other information Rehydrated reagent contains < 0,1% sodium azide.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Skin contact IF ON SKIN: Wash with soap and water.

Eye contact Rinse continuously with water for several minutes.

Ingestion IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

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

Data not available.

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

Data not available.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media Choose suitable extinguishing media according to the environment.

5.2. Special hazards arising from the substance or mixture

Possibility to small amounts of harmful gases or vapours.

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5.3. Advice for fire-fighters

Special protective equipment for fire-fighters No special protective equipment needed.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Wear protective clothing.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

In case of spillage clean with paper towel and disinfect.

6.4. Reference to other sections

See Section 8 and 13

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

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

7.2. Conditions for safe storage, including any incompatibilities

Store at +2 - 25 °C.

7.3. Specific end use(s)

No information identified.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

International OEL values Sodium azide 0,1 mg/m³ (8h) , 0,3 mg/m³ (15 min)

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8.2. Exposure controls

Hand protection

Wear protective gloves.

Skin protection

Wear protective clothing.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical state	Liquid / Solid
Colour	Colourless
Odour	Extraction Reagent 1 weakly of vinegar, other components odourless.

9.1. Information on basic physical and chemical properties

Water solubility Reagents soluble

9.2. Other information

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SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

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10.2. Chemical stability

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10.3. Possibility of hazardous reactions

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10.4. Conditions to avoid

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10.5. Incompatible materials

When in contact with acids, sodium azide forms highly toxic gas. Sodium azide reacts with metals to form explosive metal azides.

10.6 Hazardous decomposition products

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity

Quantitative data on the toxicity for this product are not available.

Sodium azide: LD50 oral (rat) 27 mg/kg, LD50 dermal (rabbit) 20 mg/kg

Sodium nitrite: LD50 oral (rat) 85 mg/kg, LC50 inhalation (rat) 5,5 mg/l

Skin irritation and corrosion

Data not available.

Skin sensitization

Data not available.

Serious eye damage and irritation

Data not available.

Respiratory irritation

Data not available.

Respiratory sensitization

Data not available.

Carcinogenicity

Data not available.

Germ cell mutagenicity

Data not available.

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Reproductive toxicity Data not available.
STOT-single exposure Data not available.
STOT-repeated exposure Data not available.
Aspiration hazard Data not available.

Repeated dose toxicity Data not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Aquatic toxicity

Quantitative data on the toxicity for this product are not available.
Fish toxicity of sodium azide: L. Macrochirus LC50 0,7 mg/l/96 h. Daphnia toxicity of sodium azide : Daphnia pulex EC50 4,2 mg/l/48 h.
Sodium nitrite: O. Mykiss LC50 0,09-0,13 mg/l/96 h. Daphnia magna EC50 12,5-100 mg/l/48 h.

Toxic effects on other organisms

Data not available.

12.2. Persistence and degradability

Data not available.

12.3. Bioaccumulative potential

Data not available.

12.4. Mobility in soil

Data not available.

12.5. Results of PBT and vPvB assessment

Data not available.

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12.6. Other adverse effects

Data not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Used product should be considered infectious and should be handled respectively.
Dispose of contents according to national and local law.
If not officially differently specified, packaging may be treated like household waste or recycled.

SECTION 14: TRANSPORT INFORMATION

14.1. UN Number

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14.2. UN Proper shipping name

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14.3. Transport hazard class(es) (ADR/RID,IMDG,ICAO/IATA)

This product is not regulated under the transport regulations.

14.4. Packing group

-

14.5. Environmental hazard

-

14.6. Special precautions for user

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

Not applicable

SECTION 15: REGULATORY INFORMATION

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

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15.2. Chemical Safety Assessment

No

SECTION 16: OTHER INFORMATION

List of H statements

H300, EUH032, H400, H410	Fatal if swallowed. Contact with acids liberates very toxic gas. Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.
H226, H314	Flammable liquid and vapour. Causes severe skin burns and eye damage.
H272, H301, H400	May intensify fire; oxidizer. Toxic if swallowed. Very toxic to aquatic life.
H300, EUH032, H400, H410	Fatal if swallowed. Contact with acids liberates very toxic gas. Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.
H300, EUH032, H400, H410	Fatal if swallowed. Contact with acids liberates very toxic gas. Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.
H300, EUH032, H400, H410	Fatal if swallowed. Contact with acids liberates very toxic gas. Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.

Training advice

Read Instructions for Use

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does

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not represent any guarantee of the properties of the product. Orion Diagnostica Oy shall not be held liable for any damage resulting from handling or from contact with the above product.

Sources of key data used to compile the Safety Data Sheet

Directive 1272/2008/EC.
SDS for Sodium azide.
SDS for Sodium nitrite.
Instructions for use.

Information which has been added, deleted or revised

Updated to meet the CLP Regulation