

SAFETY DATA SHEET

Product name: QuikRead® CRP

Catalogue No.: 135171, 135283, 133891,
135172, 135174, 135173, 135175, 136841
Supersedes edition of: -

Date of Issue: 17.9.2010

1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND THE COMPANY**1.1. Identification of the product****Product Name:** QuikRead® go CRP
Catalogue No.: 135171, 135283, 133891, 135172, 135174, 135173, 135175, 136841**Purpose of Use:** QuikRead® go CRP is a quantitative test of CRP in human whole blood, serum or plasma samples.
For IN VITRO diagnostic use only.**1.2 Manufacturer Identification****Company:** Orion Diagnostica Oy
Street address: Koivu-Mankkaan tie 6 B, FI-02200 Espoo, Finland
P.O. Box: P.O. Box 83, FI-02101 ESPOO, Finland
Phone: +358 10 4261
Telefax: +358 10 426 2794
E-mail address: product.support@oriondiagnostica.fi
VAT Reg. No.: FI 18552161**Name and address of the informant in emergency cases:** Orion Diagnostica Oy +358-10-426 3344

2. HAZARD IDENTIFICATION

The reagent caps on prefilled cuvettes contain < 1% sodium azide and is classified harmful (Xn) as specified in Directives 67/548/EEC, 1999/45/EC and 1907/2006/EC. When the reagent is reconstituted the sodium azide concentration falls to < 0,1%. This concentration is not considered harmful.

The other reagent in this kit is not hazardous as specified in Directives 67/548/EEC, 1999/45/EC and 1907/2006/EC.

Sodium azide is toxic and can be absorbed through the skin. Care should be taken to avoid ingestion, inhalation or skin contact. When in contact with acids, sodium azide forms highly toxic gas. Sodium azide reacts with metal to form explosive metal azides. Sodium azide forms toxic mixtures in water, dilution measures notwithstanding. Take relevant precaution when handling and disposing of this product.

3. COMPOSITION / INFORMATION ON INGREDIENTS**3.1 Contents:**

| | 135171, 135283, 133891, 135172, 135173 | 135174, 135175 | 136841 |
|---|--|----------------|-------------|
| CRP Reagent caps and prefilled cuvettes | 2 x 25 pcs | 20 x 25 pcs | 40 x 25 pcs |

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3.2 Hazardous ingredients:

The reagent caps on prefilled cuvettes contain < 1% sodium azide and is classified harmful (Xn). After reconstitution the concentration of sodium azide is < 0,1% which is not considered harmful concentration. The buffer in the cuvettes contains < 0,1% sodium azide as preservative.

| Cas-number | Name | Concentration | Classification | R-Phrase |
|------------|--------------|---|----------------|--------------|
| 26628-22-8 | Sodium azide | < 1% (lyophilized) < 0,1% (rehydrated and liquid reagents) | T+, N | R28-32-50/53 |

4. FIRST AID MEASURES**4.1 Special instructions:** -**4.2 Inhalation:** Fresh air**4.3 Skin contact:** Wash off with plenty of water and soap. Remove contaminated clothing.**4.4. Eye contact:** Rinse off with plenty of water (10-15 min.) the eyelid held open. If symptoms persist, seek medical care.**4.5 Ingestion:** Give plenty of water to drink. Administer activated charcoal: 20 – 40 g in 10% slurry. If symptoms persist consult a doctor.**4.6 Information for doctor or first-aid personnel:** Show this safety data sheet.**5. FIRE FIGHTING MEASURES****5.1 Suitable extinguishing media:** In adaptation to materials stored in the immediate neighbourhood.**5.2 Non-suitable extinguishing media:** -**5.3 Special exposure hazards in a fire:** Possibility to small amounts of harmful gases or vapours.**5.4 Special protective equipment:** -**5.5 Other information:** Not combustible.**6. ACCIDENTAL RELEASE MEASURES****6.1 Person-related precautionary measures:** Avoid substance contact; use suitable protective clothing.**6.2 Environmental protection measures:** No environmental hazard is anticipated provided that the material is handled and disposed of with due care.**6.3 Procedures for cleaning/absorption:****Non-used product:** Carefully take up dry. Clean up the affected area with water and detergent. Dispose of according to accepted procedures. In case of sample spillage clean with paper towel and disinfect the contaminated area.**Used product:** Spillage of potentially infectious material should be immediately removed with absorbent paper tissue and the contaminated area swabbed with a standard disinfectant. Materials used to clean spills, including gloves, should be disposed of as bio hazardous waste.**6.4 Other instructions:** The reagent contains sodium azide as preservative. Sodium azide can react with lead and copper plumbing forming highly explosive metal azides. On cleaning and disposal flush with large volumes of water to prevent azide build-up.

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7. HANDLING AND STORAGE

7.1 Handling: Only for In Vitro diagnostic use. To be handled by trained laboratory personnel. Use personal protective clothing. Do not eat, drink or smoke at workplace. Wash hands after working with substance.

7.2 Storage: At +2 - +8 °C. Consult Instructions for use.

7.3 Specific use(s): -

8. EXPOSURE CONTROL / PERSONAL PROTECTION

8.1 Exposure limit values: -

8.2 Occupational exposure control:

Respiratory protection: -

Eye protection: -

Hand protection: Protective gloves

Body protection: Protective clothing

8.3 Environmental exposure controls: -

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Form: buffer in cuvette: liquid, reagent caps contain lyophilized material

9.2 Colour: buffer: colourless

9.3 Odour: odourless

9.4 pH value: -

Melting point: N/A

Boiling point: N/A

Ignition temperature: N/A

Flash point: N/A

Explosion limits: not explosive

Density: N/A

Solubility in water: Soluble

Thermal decomposition: N/A

10. STABILITY AND REACTIVITY

10.1 Conditions to be avoided: -

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

10.3 Hazardous decomposition products during fire: -

11. TOXICOLOGICAL INFORMATION

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

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

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11.2 Irritation and corrosiveness: -**11.3 Sensitization:** -**11.4 Sub-acute, sub-chronic, prolonged toxicity:** -**11.5 Empirical data on effects on humans:** - No data are available.**11.6 Other information on health effects:** Sodium azide can be absorbed through the skin.**12. ECOLOGICAL INFORMATION****12.1 Eco-toxicity:** Quantitative data on the toxicity for this product are not available.**Aquatic toxicity:** Sodium azide is highly toxic for aquatic organisms. Sodium azide forms toxic mixtures in water, dilution measures notwithstanding and has herbicidal and nematocidal effect.**Toxic effects on other organisms:** 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/96 h.**12.2 Mobility:** Fully soluble in water.**12.3 Persistence and degradability****Biodegradation:** -**Chemical degradation:** -**12.4 Bio accumulative potential:** -**12.5 Other adverse effects:** -**13. DISPOSAL CONSIDERATIONS****General information:** Disposal of all sample and test material should be done in compliance with national, state and local regulations.**Residual / non-used product:** Prior to disposal render the reagents non-infectious by autoclaving or burning.**Used product:** Prior to disposal render the reagents/samples non-infectious by autoclaving or burning.**Packaging:** Contaminated packaging material should be considered infectious. If not officially specified differently, non-contaminated packaging may be treated like household waste or recycled.**14. TRANSPORT INFORMATION**

The product is not under the regulations of transport of hazardous goods.

15. REGULATORY INFORMATION

Labelling according to EC Directives.

Symbol: Xn Harmful**R-phrase:** 20/21/22: Harmful by inhalation, in contact with skin and if swallowed.

31: Contact with acids liberates toxic gas.

52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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S-phrases: 20/21: When using do not eat, drink or smoke.
22: Do not breathe dust.
24/25: Avoid contact with skin and eyes.
36/37: Wear suitable protective clothing and gloves.

Other information: Rehydrated and liquid reagents contain sodium azide < 0,1% which is not considered a harmful concentration.

16. OTHER INFORMATION

16.1 List of relevant R phrases:

Sodium azide: 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.

16.2 Training advice: Principles of Good Laboratory Practice should be followed. Read Instructions for Use.

16.3 Restriction of use: In Vitro diagnostic use only.

16.4 Further information: The above information is believed to be correct, but does not purport to be all inclusive and shall be used only as guide.

Products supplied by Orion Diagnostica are packed in sealed plastic/glass closures in small quantities. All reagents are contained in cartons designed to offer protection during transit and storage. Unless the products are mishandled or crushed they do not pose hazard to intermediaries. When used in laboratory in accordance with the principles of Good Laboratory Practice, good standards of occupational hygiene and instructions for use, these products are not considered to present a hazard to health.

16.5 Sources of key data used: EC Directives 67/548/EEC, 1999/45/EC and 1907/2006/EC, Instructions for use, MSDS for sodium azide, VWR International, Merck

16.6 Information that has been added, deleted or revised: -