1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Product name: CoaguChek XS Pro PT Controls
Product number: 04625382160
Business area: Near Patient Testing
Product line: None Identified
Instrument type: CoaguChek
Supplier: Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
Site Phone Number: 1-800-428-5074

2. COMPOSITION/INFORMATION ON INGREDIENTS

Description 1: PT Diluent Bulbs

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS Number</th>
<th>Weight %</th>
<th>OSHA PEL:</th>
<th>OSHA STEL:</th>
<th>ACGIH TLV:</th>
<th>ACGIH STEL:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium chloride</td>
<td>10035-04-8</td>
<td>0.1-&lt;1</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Sodium azide</td>
<td>26628-22-8</td>
<td>0.01-&lt;0.1</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>0.29 mg/m³ Ceiling 0.11 ppm Ceiling</td>
</tr>
</tbody>
</table>

Description 2: PT Levels 1 and 2 (Sodium chloride is in Level 1 only)

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS Number</th>
<th>Weight %</th>
<th>OSHA PEL:</th>
<th>OSHA STEL:</th>
<th>ACGIH TLV:</th>
<th>ACGIH STEL:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>1-5</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>HEPES</td>
<td>7365-45-9</td>
<td>1-5</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

3. HAZARDS IDENTIFICATION

Emergency Overview

NFPA Ratings: Health= 1 Flammability= 0 Reactivity= 0 Special= I
Special Definitions: A=Allergen CA=Carcinogen CO=Corrosive F=Flammable H=Harmful I=Irritant Ox=Oxidizer PB=Potential Biohazard R=Reproductive S=Sensitizer T=Toxic T+=Highly Toxic W=Water Reactive

Principle routes of exposure: Ingestion, skin and/or eye contact

Inhalation: Avoid breathing dust. May cause irritation of respiratory tract.

Ingestion: Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea

Skin contact: May cause irritation in contact with skin.

Eye contact: Contact with eyes may cause irritation

Sensitization or Odor threshold: The following chemical(s) may cause sensitization, be absorbed via skin, and/or has an odor threshold for detection:

Medical conditions aggravated by exposure: None known

Additional information: None

4. FIRST AID MEASURES

Inhalation: Consult a physician. Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Skin contact: Rinse with plenty of water. If skin irritation persists, call a physician. Remove and wash contaminated clothing before re-use

Ingestion: Consult a physician. Do not induce vomiting without medical advice

Eye contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice
5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Use dry chemical, CO2, water spray or `alcohol` foam

Unusual hazards: None known

Special protective equipment for firefighters: Wear self contained breathing apparatus for fire fighting if necessary

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Evacuate personnel to safe areas

Environmental precautions: Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.

Methods for cleaning up: Never return spills in original containers for re-use. Sweep up or vacuum (if powder) or soak up with inert absorbent material (if liquid), then place into a suitable clean, dry, closed container, and label for disposal

7. HANDLING AND STORAGE

Handling: Protect from contamination. Wear personal protective equipment

Storage: No special precautions required

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering measures: Not applicable

Personal Protective Equipment

Respiratory protection: Respiratory protection is not required under normal use of this product. If respiratory protection is needed, follow the OSHA regulation, 29CFR1910.134. Always use a NIOSH approved respirator when necessary

Hand protection: Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly

Skin and body protection: Wear appropriate body protection to prevent skin contact

Eye protection: Wear appropriate eye protection to prevent eye contact

Hygiene measures: Avoid contact with skin, eyes and clothing

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: PT Diluent Bulb = Liquid, PT Levels 1 and 2 = Solid lyophilisate

10. STABILITY AND REACTIVITY

Stability: Stable under recommended storage conditions

Polymerization: Not applicable

Hazardous decomposition products: Carbon oxides

Materials to avoid: Strong acids and strong bases. Strong oxidising agents

11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Components</th>
<th>NIOSH - Selected LD50s and LC50s:</th>
<th>NIOSH Pocket Guide - Target Organs:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium azide</td>
<td>=20 mg/kg Dermal LD50 Rabbit</td>
<td>eyes CNS skin CVS kidneys</td>
</tr>
<tr>
<td></td>
<td>=50 mg/kg Dermal LD50 Rat</td>
<td></td>
</tr>
<tr>
<td></td>
<td>=27 mg/kg Oral LD50 Rat</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>NIOSH - Selected LD50s and LC50s:</th>
<th>NIOSH Pocket Guide - Target Organs:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride</td>
<td>&gt;10 g/kg Dermal LD50 Rabbit</td>
<td></td>
</tr>
<tr>
<td></td>
<td>=3 g/kg Oral LD50 Rat</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;42 g/m³ Inhalation LC50 Rat 1h</td>
<td></td>
</tr>
</tbody>
</table>

Product number: 04625382160

Product name: CoaguChek XS Pro PT Controls
Inhalation: No additional data available  
Skin: No additional data available  
Oral: No additional data available  
Mutagenic effects: No data is available on the product itself  
Reproductive toxicity: No data is available on the product itself

12. ECOLOGICAL INFORMATION

Bioaccumulation: Not determined  
Aquatic toxicity: No data is available on the product itself  
Ecotoxicity effects: No data is available on the product itself

U.S. EPA, RCRA, CERCLA, SARA, or DGC information on persistent, bioaccumulative, and toxic chemicals (PBTs): The following chemicals are listed under the U.S. EPA regulations of RCRA, CERCLA, SARA, or DGC:

13. DISPOSAL CONSIDERATIONS

Waste from residues / unused products: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Residue from fires extinguished with this material may be hazardous

14. TRANSPORT INFORMATION

Is product hazardous to ship? No  
DOT

Proper shipping name: None  
ICTO/IATA

Proper shipping name: None  
UN Number: Not applicable  
Hazard class: Not applicable  
Subsidiary risk: Not applicable  
Packing group: Not applicable

U.S. Regulations:

U.S. CERCLA/SARA/TSCA Regulatory Information: The following chemicals are listed under the following TSCA/SARA/CERCLA lists. Refer to TSCA regulation if you need a definition for acronyms that may be shown in the TSCA Inventory field in the table below

<table>
<thead>
<tr>
<th>Components</th>
<th>CERCLA/SARA 302 RQ and TPQ (40 CFR 355, App.A)</th>
<th>CERCLA/SARA 304 RQ (40 CFR Table 302.4)</th>
<th>SARA 313 Emission reporting</th>
<th>TSCA Inventory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium azide</td>
<td>500 lb TPQ</td>
<td>1060 lb final RQ</td>
<td>Listed</td>
<td>Present</td>
</tr>
<tr>
<td></td>
<td>454 kg final RQ</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>CERCLA/SARA 302 RQ and TPQ (40 CFR 355, App.A)</th>
<th>CERCLA/SARA 304 RQ (40 CFR Table 302.4)</th>
<th>SARA 313 Emission reporting</th>
<th>TSCA Inventory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride</td>
<td>Present</td>
<td>Present</td>
<td>Present</td>
<td></td>
</tr>
<tr>
<td>HEPES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

U.S. Clean Water Act (CWA)/ California Proposition 65: The following chemicals are listed under the CWA and/or California Proposition 65:

Canadian Regulations:

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all the information required by the Controlled Products Regulations.

<table>
<thead>
<tr>
<th>Components</th>
<th>Canada - WHMIS: Classifications of Substances:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium chloride</td>
<td>D2B</td>
</tr>
</tbody>
</table>

Product number: 04625382160  
Product name: CoaguChek XS Pro PT Controls
### Components Canada - WHMIS: Classifications of Substances:

<table>
<thead>
<tr>
<th>Components</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium azide</td>
<td>D1A</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>Uncontrolled product according to WHMIS criteria</td>
</tr>
</tbody>
</table>

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**16. OTHER INFORMATION**

**Reason for revision:** Not applicable  
**References:** None  
**Additional advice:** None  
**Prepared by:** Roche Diagnostics, Health & Safety Department, MSDS Contact: 317-521-7425 or 317-521-7505

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**End of Safety Data Sheet**