SECTION 1. IDENTIFICATION

Product name : CoaguChek® XS PT Controls
Mat.-No./ Genisys-No. : 06409849160

Manufacturer or supplier’s details
Company name of supplier : Roche Diagnostics
Address : 9115 Hague Road
17250 Indianapolis IN
Telephone : 1-800-428-5074
Emergency telephone number:
In case of emergencies: CHEMTREC
Recommended use of the chemical and restrictions on use
Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section Label elements contains the resulting labelling for the kit.

GHS Label element
Not a hazardous substance or mixture.
Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

PT Level 1

GHS Classification
Not a hazardous substance or mixture.
Hazardous components
No hazardous ingredients

PT Level 2

GHS Classification
Not a hazardous substance or mixture.
Hazardous components
No hazardous ingredients
PT Bulb

GHS Classification
Not a hazardous substance or mixture.

Hazardous components
No hazardous ingredients

SECTION 4. FIRST AID MEASURES

General advice: Do not leave the victim unattended.

If inhaled: Move to fresh air.
If unconscious place in recovery position and seek medical advice.
If symptoms persist, call a physician.

In case of skin contact: If on skin, rinse well with water.

In case of eye contact: Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
If eye irritation persists, consult a specialist.

If swallowed: Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Rinse mouth with water.

Most important symptoms and effects, both acute and delayed: No information available.

Notes to physician: The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards during firefighting: No information available.

Further information: Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Special protective equipment for firefighters: Wear self-contained breathing apparatus for firefighting if necessary.
SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Avoid dust formation.

Environmental precautions: Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion: Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling: For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area.

Conditions for safe storage: Electrical installations / working materials must comply with the technological safety standards.

Materials to avoid: No materials to be especially mentioned.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

PT Level 1

Components with workplace control parameters
Contains no substances with occupational exposure limit values.

PT Level 2

Components with workplace control parameters
Contains no substances with occupational exposure limit values.

PT Bulb

Components with workplace control parameters
Contains no substances with occupational exposure limit values.

Personal protective equipment
Respiratory protection: No personal respiratory protective equipment normally required.

Hand protection
Material: Protective gloves
Remarks: The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

Eye protection: Safety glasses
Skin and body protection: Protective suit
Hygiene measures: Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

PT Level 1

Appearance: (lyophilised)
Colour: light yellow
Odour: none
Odour Threshold: No data available
pH: No data available
Melting point/range: No data available
Boiling point/boiling range: No data available
Flash point: does not flash
Evaporation rate: No data available
Flammability (solid, gas): Sustains combustion
Upper explosion limit: No data available
Lower explosion limit: No data available
Vapour pressure: No data available
Relative vapour density: No data available
Relative density: No data available
Density: No data available
Solubility(ies)
Water solubility: soluble
Partition coefficient: n-octanol/water: No data available
Auto-ignition temperature: No data available
Decomposition temperature: No data available
Viscosity : No data available
Explosive properties : No data available
Oxidizing properties : The substance or mixture is not classified as oxidizing.

**PT Level 2**

Appearance : (lyophilised)
Colour : light yellow
Odour : none
Odour Threshold : No data available
pH : No data available
Melting point/range : No data available
Boiling point/boiling range : No data available
Flash point : does not flash
Evaporation rate : No data available
Flammability (solid, gas) : Sustains combustion
Upper explosion limit : No data available
Lower explosion limit : No data available
Vapour pressure : No data available
Relative vapour density : No data available
Relative density : No data available
Density : No data available
Solubility(ies)
  Water solubility : soluble
Partition coefficient: n-octanol/water : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity : No data available
Explosive properties : No data available
Oxidizing properties : The substance or mixture is not classified as oxidizing.

**PT Bulb**

Appearance : liquid
Colour : No data available
Odour : No data available
Odour Threshold : No data available
pH : No data available
Melting point/range : No data available
Boiling point/boiling range : No data available
Flash point : does not flash
Evaporation rate: No data available
Flammability (solid, gas): The product is not flammable.
Upper explosion limit: No data available
Lower explosion limit: No data available
Vapour pressure: No data available
Relative vapour density: No data available
Relative density: No data available
Density: No data available
Solubility(ies)
- Water solubility: completely miscible
Partition coefficient: n-octanol/water: No data available
Auto-ignition temperature: No data available
Decomposition temperature: No data available
Viscosity: No data available
Explosive properties: No data available
Oxidizing properties: The substance or mixture is not classified as oxidizing.

SECTION 10. STABILITY AND REACTIVITY

Reactivity: No dangerous reaction known under conditions of normal use.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Stable under recommended storage conditions.
- No hazards to be specially mentioned.
Conditions to avoid: No data available
Incompatible materials: No data available
Hazardous decomposition products: No data available

SECTION 11. TOXICOLOGICAL INFORMATION

PT Level 1

Acute toxicity
Not classified based on available information.

Skin corrosion/irritation
Not classified based on available information.

Serious eye damage/eye irritation
Not classified based on available information.
Respiratory or skin sensitisation
Skin sensitisation: Not classified based on available information.
Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Carcinogenicity
Not classified based on available information.

IARC
No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP
No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
Not classified based on available information.

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Aspiration toxicity
Not classified based on available information.

PT Level 2

Acute toxicity
Not classified based on available information.

Skin corrosion/irritation
Not classified based on available information.

Serious eye damage/eye irritation
Not classified based on available information.

Respiratory or skin sensitisation
Skin sensitisation: Not classified based on available information.
Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Carcinogenicity
Not classified based on available information.

IARC
No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.
equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

**NTP**
No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**Reproductive toxicity**
Not classified based on available information.

**STOT - single exposure**
Not classified based on available information.

**STOT - repeated exposure**
Not classified based on available information.

**Aspiration toxicity**
Not classified based on available information.

**PT Bulb**

**Acute toxicity**
Not classified based on available information.

**Product:**

**Acute dermal toxicity**
Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

**Skin corrosion/irritation**
Not classified based on available information.

**Serious eye damage/eye irritation**
Not classified based on available information.

**Respiratory or skin sensitisation**
Skin sensitisation: Not classified based on available information.
Respiratory sensitisation: Not classified based on available information.

**Germ cell mutagenicity**
Not classified based on available information.

**Carcinogenicity**
Not classified based on available information.

**IARC**
No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**
No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

**NTP**
No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**Reproductive toxicity**
Not classified based on available information.
STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Aspiration toxicity
Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

**PT Level 1**

Ecotoxicity

**Product:**
Ecotoxicology Assessment
Acute aquatic toxicity : This product has no known ecotoxicological effects.
Chronic aquatic toxicity : This product has no known ecotoxicological effects.
Toxicity Data on Soil : Not expected to adsorb on soil.
Other organisms relevant to the environment : No data available

Persistence and degradability
No data available

Bioaccumulative potential
No data available

Mobility in soil
No data available

Other adverse effects

**Product:**
Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

**PT Level 2**

Ecotoxicity

**Product:**
Ecotoxicology Assessment
Acute aquatic toxicity : This product has no known ecotoxicological effects.
Chronic aquatic toxicity : This product has no known ecotoxicological effects.
Toxicity Data on Soil : Not expected to adsorb on soil.
SAFETY DATA SHEET

CoaguChek® XS PT Controls

Version: 1.5  Revision Date: 04-24-2015  Date of last issue: 09-18-2014
Date of first issue: 06-04-2012

Other organisms relevant to the environment: No data available

**Persistence and degradability**
No data available

**Bioaccumulative potential**
No data available

**Mobility in soil**
No data available

**Other adverse effects**

**Product:**
Ozone-Depletion Potential: Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

**PT Bulb**

**Ecotoxicity**

**Product:**
Ecotoxicology Assessment
Acute aquatic toxicity: This product has no known ecotoxicological effects.
Chronic aquatic toxicity: This product has no known ecotoxicological effects.
Toxicity Data on Soil: Not expected to adsorb on soil.
Other organisms relevant to the environment: No data available

**Persistence and degradability**
No data available

**Bioaccumulative potential**
No data available

**Mobility in soil**
No data available

**Other adverse effects**

**Product:**
Ozone-Depletion Potential: Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: The product has to be disposed of as laboratory chemical in accordance with local regulations.

Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulation

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

PT Level 1

TSCA list: Not relevant

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 311/312 Hazards: No SARA Hazards

SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act
This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

**Clean Water Act**
This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307.

**Massachusetts Right To Know**
No components are subject to the Massachusetts Right to Know Act.

**Pennsylvania Right To Know**
Animal serum /-plasma /- hemolysate - different species, lyophilized
Hepes, Hemisodium
Not Assigned
90 - 100 %
103404-87-1
5 - 10 %

**New Jersey Right To Know**
Animal serum /-plasma /- hemolysate - different species, lyophilized
Hepes, Hemisodium
Not Assigned
90 - 100 %
103404-87-1
5 - 10 %

**California Prop 65**
This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

**The components of this product are reported in the following inventories:**

**REACH**
: Not in compliance with the inventory
  : Animal serum /-plasma /- hemolysate - different species, lyophilized
  : Hepes, Hemisodium

**CH INV**
: Not in compliance with the inventory
  : Animal serum /-plasma /- hemolysate - different species, lyophilized
  : Hepes, Hemisodium

**TSCA**
: Not On TSCA Inventory
  : Animal serum /-plasma /- hemolysate - different species, lyophilized
  : Hepes, Hemisodium

**DSL**
: This product contains the following components that are not on the Canadian DSL nor NDSL.
<table>
<thead>
<tr>
<th>Inventory</th>
<th>Compliance Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>Not in compliance with the inventory</td>
<td>Animal serum /-plasma /- hemolysate - different species, lyophilized / Heps, Hemisodium</td>
</tr>
<tr>
<td>NZIoC</td>
<td>On the inventory, or in compliance with the inventory</td>
<td></td>
</tr>
<tr>
<td>ENCS</td>
<td>Not in compliance with the inventory</td>
<td></td>
</tr>
<tr>
<td>ISHL</td>
<td>Not in compliance with the inventory</td>
<td></td>
</tr>
<tr>
<td>KECl</td>
<td>Not in compliance with the inventory</td>
<td></td>
</tr>
<tr>
<td>PICCS</td>
<td>Not in compliance with the inventory</td>
<td></td>
</tr>
<tr>
<td>IECSC</td>
<td>Not in compliance with the inventory</td>
<td></td>
</tr>
</tbody>
</table>

**Inventories**

AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECl (Korea), NZIoC (New Zealand), PICCS (Philippines), TSCA (USA)

**PT Level 2**

**TSCA list** : Not relevant
EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act
This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B). This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61). This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F). This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act
This product does not contain any Hazardous Substances listed under the U.S. Clean Water Act, Section 311, Table 116.4A. This product does not contain any Hazardous Chemicals listed under the U.S. Clean Water Act, Section 311, Table 117.3. This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307.

Massachusetts Right To Know
No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal serum /-plasma /- hemolysate - different species, lyophilized</td>
<td>103404-87-1</td>
<td>5 - 10 %</td>
</tr>
<tr>
<td>Hepes, Hemisodium</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

New Jersey Right To Know

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal serum /-plasma /- hemolysate - different species, lyophilized</td>
<td>103404-87-1</td>
<td>5 - 10 %</td>
</tr>
<tr>
<td>Hepes, Hemisodium</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

California Prop 65
This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

The components of this product are reported in the following inventories:
REACH : Not in compliance with the inventory.
<table>
<thead>
<tr>
<th>Section</th>
<th>Compliance Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CH INV</td>
<td>Not in compliance with the inventory</td>
<td>Animal serum /-plasma /- hemolysate - different species, ly-</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ophilized</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Heparin, Hemisodium</td>
</tr>
<tr>
<td>TSCA</td>
<td>Not On TSCA Inventory</td>
<td>Animal serum /-plasma /- hemolysate - different species, ly-</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ophilized</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Heparin, Hemisodium</td>
</tr>
<tr>
<td>DSL</td>
<td>This product contains the following</td>
<td>Animal serum /-plasma /- hemolysate - different species, ly-</td>
</tr>
<tr>
<td></td>
<td>components that are not on the</td>
<td>ophilized</td>
</tr>
<tr>
<td></td>
<td>Canadian DSL nor NDSL</td>
<td>Heparin, Hemisodium</td>
</tr>
<tr>
<td>AICS</td>
<td>Not in compliance with the inventory</td>
<td>Animal serum /-plasma /- hemolysate - different species, ly-</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ophilized</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Heparin, Hemisodium</td>
</tr>
<tr>
<td>NZIoC</td>
<td>On the inventory, or in compliance</td>
<td>Animal serum /-plasma /- hemolysate - different species, ly-</td>
</tr>
<tr>
<td></td>
<td>with the inventory</td>
<td>ophilized</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Heparin, Hemisodium</td>
</tr>
<tr>
<td>ENCS</td>
<td>Not in compliance with the inventory</td>
<td>Animal serum /-plasma /- hemolysate - different species, ly-</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ophilized</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Heparin, Hemisodium</td>
</tr>
<tr>
<td>ISHL</td>
<td>Not in compliance with the inventory</td>
<td>Animal serum /-plasma /- hemolysate - different species, ly-</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ophilized</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Heparin, Hemisodium</td>
</tr>
<tr>
<td>KECI</td>
<td>Not in compliance with the inventory</td>
<td>Animal serum /-plasma /- hemolysate - different species, ly-</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ophilized</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Heparin, Hemisodium</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

CoaguChek® XS PT Controls

Version: 1.5
Revision Date: 04-24-2015
Date of last issue: 09-18-2014
Date of first issue: 06-04-2012

PICCS: Not in compliance with the inventory
- Animal serum/-plasma/-hemolysate - different species, lyophilized
- Hepses, Hemisodium

IECSC: Not in compliance with the inventory
- Animal serum/-plasma/-hemolysate - different species, lyophilized

Inventories
AIICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TSCA (USA)

PT Bulb
TSCA list: Not relevant

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component RQ (lbs)</th>
<th>Calculated product RQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium azide</td>
<td>26628-22-8</td>
<td>1000</td>
<td>*</td>
</tr>
</tbody>
</table>

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component RQ (lbs)</th>
<th>Calculated product RQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium azide</td>
<td>26628-22-8</td>
<td>1000</td>
<td>*</td>
</tr>
</tbody>
</table>

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 311/312 Hazards: No SARA Hazards

SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act
This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).
Clean Water Act
This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know
sodium azide 26628-22-8 0 - 0.1%

Pennsylvania Right To Know
water 7732-18-5 90 - 100%
sodium azide 26628-22-8 0 - 0.1%

New Jersey Right To Know
water 7732-18-5 90 - 100%

California Prop 65
This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

The components of this product are reported in the following inventories:
REACH : Not in compliance with the inventory
: calcium chloride
: sodium azide
CH INV : On the inventory, or in compliance with the inventory
TSCA : On TSCA Inventory
DSL : All components of this product are on the Canadian DSL.
AICS : On the inventory, or in compliance with the inventory
NZIoC : On the inventory, or in compliance with the inventory
ENCS : Not in compliance with the inventory
: water
ISHL : Not in compliance with the inventory
: water
KECI : On the inventory, or in compliance with the inventory
PICCS : On the inventory, or in compliance with the inventory
IECSC : On the inventory, or in compliance with the inventory

Inventories
CoaguChek® XS PT Controls

Version 1.5
Revision Date: 04-24-2015
Date of last issue: 09-18-2014
Date of first issue: 06-04-2012

AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TSCA (USA)

PT Level 1

GHS Label element
Not a hazardous substance or mixture.

PT Level 2

GHS Label element
Not a hazardous substance or mixture.

PT Bulb

GHS Label element
Not a hazardous substance or mixture.

SECTION 16. OTHER INFORMATION

Further information

PT Level 1
NFPA:
Flammability
Health
Instability
0

0

0

Special hazard.

HMIS III:

HEALTH
0
FLAMMABILITY
0
PHYSICAL HAZARD
0

0 = not significant, 1 = Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

PT Level 2
NFPA:
Flammability
Health
Instability
0

0

0

Special hazard.

HMIS III:

HEALTH
0
FLAMMABILITY
0
PHYSICAL HAZARD
0

0 = not significant, 1 = Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

PT Bulb
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / EN