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# Material Safety Data Sheet



## 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

**Emergency telephone number:**  
CHEMTREC:  
1-800-424-9300 (U.S. or Canada)  
1-703-527-3887 (International)

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Description 1: PT Diluent Bulbs

Components	CAS Number	Weight %	OSHA PEL:	OSHA STEL:	ACGIH TLV:	ACGIH STEL:
Calcium chloride	10035-04-8	0.1-<1	NA	NA	NA	NA
Sodium azide	26628-22-8	0.01-<0.1	NA	NA	NA	0.29 mg/m <sup>3</sup> Ceiling 0.11 ppm Ceiling

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

Components	CAS Number	Weight %	OSHA PEL:	OSHA STEL:	ACGIH TLV:	ACGIH STEL:
Sodium chloride	7647-14-5	1-5	NA	NA	NA	NA
HEPES	7365-45-9	1-5	NA	NA	NA	NA

## 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

Notes to physician: None determined

## 5. FIRE-FIGHTING MEASURES

**Suitable extinguishing media:** Use dry chemical, CO<sub>2</sub>, 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

Components	NIOSH - Selected LD50s and LC50s:	NIOSH Pocket Guide - Target Organs:
Sodium azide	=20 mg/kg Dermal LD50 Rabbit =50 mg/kg Dermal LD50 Rat =27 mg/kg Oral LD50 Rat	eyes CNS skin CVS kidneys

Components	NIOSH - Selected LD50s and LC50s:	NIOSH Pocket Guide - Target Organs:
Sodium chloride	>10 g/kg Dermal LD50 Rabbit =3 g/kg Oral LD50 Rat >42 g/m <sup>3</sup> Inhalation LC50 Rat 1h	

**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**

<b>Proper shipping name:</b> None			
<b>UN Number:</b> Not applicable	<b>Hazard class:</b> Not applicable	<b>Subsidiary risk:</b> Not applicable	<b>Packing group:</b> Not applicable

**ICAO/IATA**

<b>Proper shipping name:</b> None			
<b>UN Number:</b> Not applicable	<b>Hazard class:</b> Not applicable	<b>Subsidiary risk:</b> Not applicable	<b>Packing group:</b> Not applicable

**15. REGULATORY INFORMATION**

**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

Components	CERCLA/SARA 302 RQ and TPQ (40 CFR 355, App.A)	CERCLA/SARA 304 RQ (40 CFR Table 302.4)	SARA 313 Emission reporting	TSCA Inventory
Sodium azide	500 lb TPQ	1000 lb final RQ 454 kg final RQ	Listed	Present

Components	CERCLA/SARA 302 RQ and TPQ (40 CFR 355, App.A)	CERCLA/SARA 304 RQ (40 CFR Table 302.4)	SARA 313 Emission reporting	TSCA Inventory
Sodium chloride				Present
HEPES				Present

**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.

Components	Canada - WHMIS: Classifications of Substances:
Calcium chloride	D2B

<b>Components</b>	<b>Canada - WHMIS: Classifications of Substances:</b>
Sodium azide	D1A

<b>Components</b>	<b>Canada - WHMIS: Classifications of Substances:</b>
Sodium chloride	Uncontrolled product according to WHMIS classification criteria

**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**