SAFETY DATA SHEET

CoaguChek XS PT Test

Version 1.1  
Revision Date: 12-08-2015  
Date of last issue: 11-18-2015  
Date of first issue: 11-18-2015

SECTION 1. IDENTIFICATION

Product name: CoaguChek XS PT Test
Mat.-No./ Genisys-No.: 07797826160

Manufacturer or supplier's details
Company name of supplier: Roche Diagnostics
Address: 9115 Hague Road 46250 Indianapolis IN
Telephone: 1-800-428-5074
Emergency telephone: CHEMTREC 1-800-424-9300 (U.S. or Canada) 1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use
Restrictions on use: For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Not a hazardous substance or mixture.

GHS Label element
Not a hazardous substance or mixture.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture
Substance name: Strips

Hazardous ingredients
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. FIRE-FIGHTING MEASURES

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

Specific hazards during firefighting: No information available.

Hazardous combustion products: No hazardous combustion products are known.

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

Special protective equipment for fire-fighters: 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
SAFETY DATA SHEET

CoaguChek XS PT Test

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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.

Technical measures/Precautions: See label, package insert or internal guidelines

Materials to avoid: No materials to be especially mentioned.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

Engineering measures: No data available

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

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

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

Appearance: solid
Color: No data available
Odor: Not applicable
Odor Threshold: Not applicable
pH: Not applicable
Melting point/range: No data available
Boiling point/boiling range: No data available
Flash point: Not applicable
Evaporation rate: No data available
Upper explosion limit: No data available
Lower explosion limit: No data available
Vapor pressure: No data available
Relative vapor density: Not applicable
Relative density: No data available
Solubility(ies)
   Water solubility: insoluble
   Solubility in other solvents: No data available
Partition coefficient: n-octanol/water: No data available
Autoignition temperature: No data available
Decomposition temperature: No data available
Viscosity
   Viscosity, dynamic: Not applicable
   Viscosity, kinematic: Not applicable

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
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 sensitization
Skin sensitization: Not classified based on available information.
Respiratory sensitization: Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Carcinogenicity
Not classified based on available information.

IARC
No ingredient 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 ingredient 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 ingredient 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

Ecotoxicity
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 Pro-
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

UNRTDG
Not regulated as a dangerous good

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.

Domestic regulation

49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

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.
SAFETY DATA SHEET

CoaguChek XS PT Test

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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 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

US State Regulations

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

Pennsylvania Right To Know
non hazardous compounds Not Assigned 90 - 100 %

New Jersey Right To Know
non hazardous compounds Not Assigned 90 - 100 %

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

The ingredients of this product are reported in the following inventories:

CH INV : Not in compliance with the inventory non hazardous compounds

TSCA : Not On TSCA Inventory non hazardous compounds

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL. non hazardous compounds

AICS : Not in compliance with the inventory non hazardous compounds

NZIoC : On the inventory, or in compliance with the inventory

ENCS : Not in compliance with the inventory non hazardous compounds
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ISHL: Not in compliance with the inventory non hazardous compounds
KECI: Not in compliance with the inventory non hazardous compounds
PICCS: Not in compliance with the inventory non hazardous compounds
IECSC: Not in compliance with the inventory non hazardous compounds

TSCA list
No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

(Q)SAR - (Quantitative) Structure Activity Relationship; ASTM - American Society for the Testing of Materials; bw - Body weight; DIN - Standard of the German Institute for Standardisation; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISO - International Organisation for Standardization; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative; DSL - Domestic Substances List (Canada); KECI - Korea Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); AICS - Australian Inventory of Chemical Substances; IECSC - Inventory of Existing Chemical Substances in China; ENCS - Existing and New Chemical Substances (Japan); ISHL - Industrial Safety and Health Law (Japan); PICCS - Philippines Inventory of Chemicals and Chemical Substances; NZIoC - New Zealand Inventory of Chemicals; TCSI - Taiwan Chemical Substance Inventory; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; DOT - Department of Transportation; EHS - Extremely Hazardous Substance; HMIS - Hazardous Materials Identification System; MSHA - Mine Safety and Health Administration; NFPA - National Fire Protection Association; RCRA - Resource Conservation and Recovery Act; RQ - Reportable Quantity; SARA - Superfund Amendments and Reauthorization Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; GLP - Good Laboratory Practice; ERG - Emergency Response Guide; NTP - National Toxicology Program; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods
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