

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



CoaguChek XS 2x24 tests USA (en)

Version 1.0

Revision Date 05-08-2012

Print Date 11-16-2012

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

Commercial Product Name : CoaguChek XS PT
Mat.-No./ Genisys-No. : 04625315160

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended restrictions on use : For professional users only.

1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics
9115 Hague Road
46250 Indianapolis IN

E-mail address :
Telephone : 1-800-428-5074
Telefax :
Responsible Department :
In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or
Canada)
1-703-527-3887 (International)

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

Classification (67/548/EEC, 1999/45/EC)

Not a hazardous substance or mixture according to EC-directives 67/548/EEC or 1999/45/EC.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

2.3 Other hazards

No information available.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

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Remarks : No dangerous ingredients according to Regulation (EC) No. 1907/2006

SECTION 4. FIRST AID MEASURES

4.1 Description of first aid measures

- General advice : Do not leave the victim unattended.
- If inhaled : 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.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

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

SECTION 5. FIREFIGHTING MEASURES

5.1 Extinguishing media

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

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting : No information available.

5.3 Advice for firefighters

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

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Avoid dust formation.

6.2 Environmental precautions

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

6.3 Methods and materials for containment and cleaning up

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

6.4 Reference to other sections

Treat recovered material as described in the section "Disposal considerations".

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

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

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

7.2 Conditions for safe storage, including any incompatibilities

Further information on storage conditions : See label or package insert

7.3 Specific end uses

Specific use(s) : Laboratory chemicals

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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Exposure Guidelines

Contains no substances with occupational exposure limit values.

Eye protection : Safety glasses

Hand protection :
Protective gloves

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.

Skin and body protection : Protective suit

Respiratory protection : No personal respiratory protective equipment normally required.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance : solid

Melting point/range : no data available

Boiling point/boiling range : no data available

Flash point : not applicable

Lower explosion limit : no data available

Upper explosion limit : no data available

Vapour pressure : no data available

Water solubility : insoluble



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Partition coefficient: n-
octanol/water : no data available

Ignition temperature : no data available

Thermal decomposition : no data available

Viscosity, dynamic : no data available

9.2 Other information

Conductivity : no data available

Oxidising potential : no data available

Surface tension : no data available

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Further information: Stable under recommended storage conditions., No hazards to be specially mentioned.

10.4 Conditions to avoid

Conditions to avoid : no data available

10.5 Incompatible materials

Materials to avoid : no data available

10.6 Hazardous decomposition products

Hazardous decomposition
products : no data available

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Product

Acute oral toxicity : no data available

Acute inhalation toxicity : no data available

Acute dermal toxicity : no data available



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Acute toxicity (other routes of administration) : no data available

Aspiration toxicity : no data available

SECTION 12. ECOLOGICAL INFORMATION

12.1 Toxicity

Product:

Toxicity to fish : no data available
Toxicity to daphnia and other aquatic invertebrates : no data available

Toxicity to algae : no data available

Toxicity to bacteria : no data available

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : no data available

12.2 Persistence and degradability

Product:

Biodegradability : no data available

12.3 Bioaccumulative potential

Product:

Bioaccumulation : no data available

12.4 Mobility in soil

Product:

Mobility : no data available
Distribution among environmental compartments : no data available
Environmental fate and pathways : no data available
Physico-chemical removability : no data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance is not considered to be persistent, bioaccumulating nor toxic (PBT)., This substance is not

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considered to be very persistent nor very bioaccumulating (vPvB).

12.6 Other adverse effects

Product:

Biochemical Oxygen Demand (BOD) : no data available

Dissolved organic carbon (DOC) : no data available

Chemical Oxygen Demand (COD) : no data available

Adsorbed organic bound halogens (AOX) : no data available

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product : 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

DOT

Not dangerous goods

IATA

Not dangerous goods

IMDG

Not dangerous goods

SECTION 15. REGULATORY INFORMATION

OSHA Hazards : No OSHA Hazards

WHMIS Classification : Not Rated

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This product has been classified according to the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

CERCLA Reportable Quantity

Product : This material does not contain any components with a CERCLA RQ.

SARA 302 Reportable Quantity

Product : This material does not contain any components with a SARA 302 RQ.

SARA 311/312 Hazards : No SARA Hazards

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

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

SARA 304 : This material does not contain any components with a section 304 EHS RQ.

Clean Air Act

Ozone-Depletion Potential : 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 chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

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.

US State Regulations

Massachusetts Right To Know

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



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Pennsylvania Right To Know

Components : non hazardous compounds - 100 %

New Jersey Right To Know

Components : non hazardous compounds - 100 %

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

SECTION 16. OTHER INFORMATION

Further information

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 a 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.