SAFETY DATA SHEET

Cardiac Control Troponin T

Version: 1.4
Revision Date: 04-24-2015
Date of last issue: 09-18-2014
Date of first issue: 10-09-2013

SECTION 1. IDENTIFICATION

Product name: Cardiac Control Troponin T
Mat.-No./ Genisys-No.: 11937553193
Chemical nature: Handle as potentially infectious.

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 number:
In case of emergencies: 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
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
Hazard pictograms: !

Signal word: Warning
Hazard statements: H317 May cause an allergic skin reaction.
Precautionary statements: Prevention:
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.
Response:
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Cal. neg - level 1**

**GHS Classification**
Skin sensitisation: H317: May cause an allergic skin reaction.
Category 1
Chemical nature: Handle as potentially infectious.

**Hazardous components**

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS-No.</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-methyl-2H-isothiazol-3-one hydrochloride</td>
<td>26172-54-3</td>
<td>&gt;= 0.1 - &lt; 1</td>
</tr>
</tbody>
</table>

**Cal. low - level 2**

**GHS Classification**
Skin sensitisation: H317: May cause an allergic skin reaction.
Category 1
Chemical nature: Handle as potentially infectious.

**Hazardous components**

<table>
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<tr>
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SECTION 4. FIRST AID MEASURES

**General advice**
Move out of dangerous area.
Show this safety data sheet to the doctor in attendance.
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.
Keep eye wide open while rinsing.
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:** None known.

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

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**SECTION 5. FIREFIGHTING MEASURES**

- **Suitable extinguishing media:** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- **Unsuitable extinguishing media:** High volume water jet
- **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.

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**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- **Personal precautions, protective equipment and emergency procedures:** Use personal protective equipment. Refer to protective measures listed in sections 7 and 8.
- **Environmental precautions:** Prevent product from entering drains. Prevent further leakage or spillage if safe to do so. Local authorities should be advised if significant spillages cannot be contained.
- **Methods and materials for containment and cleaning up:** Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Keep in suitable, closed containers for disposal.

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**SECTION 7. HANDLING AND STORAGE**

- **Advice on protection against fire and explosion:** Normal measures for preventive fire protection.
- **Advice on safe handling:** Do not breathe vapours/dust. Avoid exposure - obtain special instructions before use. Avoid contact with skin and eyes. For personal protection see section 8. Smoking, eating and drinking should be prohibited in the ap-
application area. Dispose of rinse water in accordance with local and national regulations. Persons susceptible to skin sensitisation problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

Conditions for safe storage: Keep container tightly closed in a dry and well-ventilated place. Electrical installations / working materials must comply with the technological safety standards.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Cal. neg - level 1

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

Hazardous components without workplace control parameters

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<td>hydrochloride</td>
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Cal. low - level 2

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

Hazardous components without workplace control parameters

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Personal protective equipment

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: Eye wash bottle with pure water Tightly fitting safety goggles
Skait the natural text from the document.
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: does not flash
Evaporation rate: No data available
Flammability (solid, gas): No data available
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: No decomposition if stored and applied as directed.

**SECTION 11. TOXICOLOGICAL INFORMATION**

**Cal. neg - level 1**

Acute toxicity
Not classified based on available information.

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

Skin corrosion/irritation
Not classified based on available information.

**Product:**
Remarks: May cause skin irritation and/or dermatitis.
Components:
2-methyl-2H-isothiazol-3-one hydrochloride:
Result: Causes burns.

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

Product:
Remarks: Vapours may cause irritation to the eyes, respiratory system and the skin.

Respiratory or skin sensitisation
Skin sensitisation: May cause an allergic skin reaction.
Respiratory sensitisation: Not classified based on available information.

Product:
Remarks: Causes sensitisation.

Components:
2-methyl-2H-isothiazol-3-one hydrochloride:
Assessment: May cause sensitisation by skin contact.

Assessment: May cause sensitisation by inhalation.

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.
Cal. low - level 2
Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

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

Skin corrosion/irritation
Not classified based on available information.

Product:
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Aspiration toxicity
Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

Cal. neg - level 1

Ecotoxicity

Components:
2-methyl-2H-isothiazol-3-one hydrochloride:
Ecotoxicology Assessment
Acute aquatic toxicity : This product has no known ecotoxicological effects.
Chronic aquatic toxicity : This product has no known ecotoxicological effects.

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).

Cal. low - level 2

Ecotoxicity

Components:
2-methyl-2H-isothiazol-3-one hydrochloride:
Ecotoxicology Assessment
Acute aquatic toxicity : This product has no known ecotoxicological effects.
Chronic aquatic toxicity: This product has no known ecotoxicological effects.

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: Special treatment as infectious material is mandatory in compliance with local regulations (disinfection and incineration). Do not contaminate ponds, waterways or ditches with chemical or used container. Send to a licensed waste management company. Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging: Empty remaining contents. Dispose of as unused product. 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
SECTION 15. REGULATORY INFORMATION

*Cal. neg - 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 SOCMII 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**

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<tr>
<th>Substance</th>
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<th>% in Material</th>
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**New Jersey Right To Know**

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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
- Human serum /-plasma / -hemolysate, liquid
- sodium chloride
- Sodium citrate
- Citric acid monohydrate
- hydroxyl-2-pyridone
- 2-methyl-2H-isothiazol-3-one hydrochloride

CH INV
- Not in compliance with the inventory
- Human serum /-plasma / -hemolysate, liquid

TSCA
- Not On TSCA Inventory
- Human serum /-plasma / -hemolysate, liquid
- hydroxyl-2-pyridone

DSL
- This product contains the following components that are not on the Canadian DSL nor NDSL.
- Human serum /-plasma / -hemolysate, liquid
- hydroxyl-2-pyridone

AICS
- Not in compliance with the inventory
- Human serum /-plasma / -hemolysate, liquid
- hydroxyl-2-pyridone

NZIoC
- Not in compliance with the inventory
- hydroxyl-2-pyridone

ENCS
- Not in compliance with the inventory
- Human serum /-plasma / -hemolysate, liquid
- water
**SAFE DATA SHEET**

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| ISHL | : hydroxyl-2-pyridone | : 2-methyl-2H-isothiazol-3-one hydrochloride |
| KECI | : Not in compliance with the inventory | : Human serum /-plasma / -hemolysate, liquid |
|      | : hydroxyl-2-pyridone       | : 2-methyl-2H-isothiazol-3-one hydrochloride |
| PICCS| : Not in compliance with the inventory | : Human serum /-plasma / -hemolysate, liquid |
|      | : hydroxyl-2-pyridone       | |
| IECSC| : Not in compliance with the inventory | : Human serum /-plasma / -hemolysate, liquid |
|      | : hydroxyl-2-pyridone       | |

**Inventories**

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

**Cal. low - 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.
SAFETY DATA SHEET

Cardiac Control Troponin T

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

Pennsylvania Right To Know

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<tr>
<td>Human serum /-plasma /-hemolysate, liquid water</td>
<td>7732-18-5</td>
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</tr>
<tr>
<td>sodium chloride</td>
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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

- Human serum /-plasma /-hemolysate, liquid
- sodium chloride
- Sodium citrate
- Citric acid monohydrate
- hydroxyl-2-pyridone
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: Human serum /-plasma / -hemolysate, liquid
: hydroxyl-2-pyridone
: non hazardous compounds (liquid)

IECSC: Not in compliance with the inventory
: Human serum /-plasma / -hemolysate, liquid
: hydroxyl-2-pyridone
: non hazardous compounds (liquid)

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

Cal. neg - level 1

GHS Label element
Hazard pictograms

Signal word: Warning
Hazard statements: H317 May cause an allergic skin reaction.
Precautionary statements: Prevention:
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.
Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P363 Wash contaminated clothing before reuse.

**Disposal:**
P501 Dispose of contents/ container to an approved waste disposal plant.

**Cal. low - level 2**

**GHS Label element**

**Hazard pictograms**

![Exclamation Mark]

**Signal word**

Warning

**Hazard statements**

H317 May cause an allergic skin reaction.

**Precautionary statements**

**Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.

**Response:**
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P363 Wash contaminated clothing before reuse.

**Disposal:**
P501 Dispose of contents/ container to an approved waste disposal plant.

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**SECTION 16. OTHER INFORMATION**

**Further information**

**Cal. neg - level 1**

**NFPA:**

- **Flammability:**
  - Health: 2
  - Instability: 0

**HMIS III:**

- **HEALTH:** 2
- **FLAMMABILITY:** 1
- **PHYSICAL HAZARD:** 0

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

**Cal. low - level 2**
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.