



Material Safety Data Sheet

Effective Date: November 23rd, 2011

Supersedes: Not applicable

CT / NG Assay

1. Product and Company Identification

Product name: GeneXpert CT / NG Assay

Product number: RCT/NG-10, 900-0529

Manufacturer:
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Telephone Numbers:
(888) 838-3222 (6 AM – 5 PM Pacific time US)

Outside of the US: 1 (408) 541-4191

24-Hour Emergency Telephone:

CHEMTREC (800) 424-9300

Outside of the US: 1 (703) 741-5500

E-mail: techsupport@cepheid.com

Relevant identified uses of the mixture and uses advised against:

The following SDS is for the final finished product only as used in the laboratory. It contains seven (7) components, some of which are in freeze-dried powders and reagents which are contained in the cartridge. The Binding reagent is contained in an ampoule. All reagents are clear, colorless liquids. Exemptions for disclosing some component information are pursuant to CLP Article 1(5)(d) and 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).

2. Hazards Identification

Note: The below applies to the Lysis Reagent containing Guanidinium thiocyanate

Classification of the substance or mixture: Acute toxicity, oral (Category 5)
Chronic aquatic toxicity (Category 4)

Regulation (EC) 1272/2008 [GHS]

Label Elements (See section 15 of this SDS)

CLP/GHS hazard pictogram None required

CLP/GHS signal word Warning



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**CLP/GHS
Hazard
and Precautionary
statements**

H303 – May be harmful if swallowed. H413 – May cause long lasting harmful effects to aquatic life.

P264 - Wash hands thoroughly after handling. P280 - Wear protective gloves/eye protection/face protection. P273 - Avoid release to the environment. P302 + P352 – IF ON SKIN: Wash with plenty of soap and water. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312 – Call a POISON CENTER or physician if you feel unwell. P501 - Dispose of contents/container to location in accordance with local and regional/national/international regulations.

US Hazard Overview Lysis Reagent contains Guanidinium thiocyanate.

Note The GHS classifications are based on Regulation EC 1272/2008 (EU CLP) and the calculation procedure of the ‘Globally Harmonized System of Classification and Labelling of Chemicals (GHS)’ in the latest version.

3. Composition Information on Ingredients

This product consists of a cartridge with three beads to which aqueous reagents are added as part of an assay. There are seven parts - Three components are beads, and four reagents are clear, colorless liquids.

The following classifications (EU Risk phrases and CLP/GHS H-phrases) apply to the Lysis Reagent.

Lysis reagent is a clear, colorless liquid with the following hazardous ingredients:

Ingredient	CAS#	EINECs / ELINCS #	% Composition	EU Risk Phrase	CLP/GHS Classification
Guanidinium thiocyanate	593-84-0	209-812-1	< 30	R22, R32, R58	H303, H413



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TE Reagent, Wash Reagent, Binding Reagent, and beads each are at concentrations less than 1% in the mixture or not considered hazardous under US hazard communication regulations (29 CFR 1910.1200), EU directives for classification and labeling of substances or mixtures or the Global Harmonization System for classification and labeling of substances or mixtures.

4. First Aid Measures

- Eye:** May cause eye irritation. Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Consult a physician.
- Skin:** May cause skin irritation. Wash with plenty of soap and water. Consult a physician.
- Ingestion:** Rinse mouth with water. Never give anything by mouth to an unconscious person. Consult a physician.
- Inhalation:** If breathing difficulty should occur, remove person to fresh air and consult a physician.

5. Fire Fighting Measures

Extinguishing Media: Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.

Specific hazards arising

from substance or mixture: May emit toxic fumes of carbon oxides, sulfur oxides, nitrogen oxides.

Flammability/Explosivity: None expected.

Advice for Firefighters: Wear full protective clothing and a self-contained breathing apparatus if necessary.

Hazardous

Decomposition Products: See Section 10.

6. Accidental Release Measures

If product/material is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment. For small spills, wear gloves and absorb spill with paper towel. Do not dispose spilled materials down drain. Dispose of material according to local, State and Federal waste disposal regulations (see Section 13).

Material Safety Data Sheet

Effective Date: November 23rd, 2011

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CT/NG Assay

7. Handling and Storage

Handling Precautions: Avoid skin and eye contact.

Storage Requirements: Store according to product labeling.

8. Exposure Controls/Personal Protection

Occupational Exposure Limits: Guanidinium thiocyanate has no known occupational exposure limit values.

Engineering Controls: None normally required.

Eye Protection: Wear safety glasses with side shields or chemical splash goggles. Base the choice of protection on the job activity and potential for contact with eyes or face.

Respiratory Protection: None normally required.

Skin Protection: In laboratory setting, wear gloves and lab coat at a minimum to minimize skin contact. Base the choice of protection on the job activity and potential for skin contact.

Other: Facilities storing or using this product should be equipped with a sink and eyewash station. Wash hands and other potentially exposed areas immediately after handling material (especially before eating, drinking, or smoking).

9. Physical and Chemical Properties

Appearance: Beads are solid white components in cartridges; reagents are clear liquids which are primarily buffered in aqueous solutions.

Odor: Components are odorless

Odor threshold: No information identified.

pH: 6.6 – 8.8 (solids and other liquid reagents)

Melting point/freezing point: Liquid reagents near 0 °C.

Initial boiling point and boiling range: Liquid reagents near 100 °C.

Flash point: 360 – 560 F (Binding reagent)

Evaporation rate: Minimal

Flammability (solid, gas): No information identified.

Upper/lower flammability or explosive limits: No information identified.

Vapor pressure: Minimal

Vapor density: No information identified.

Relative density: No information identified.

Water solubility: Reagents are already aqueous; beads are soluble in aqueous solutions.



Material Safety Data Sheet

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Partition coefficient: n-octanol/water: No information identified.

Auto-ignition temperature: No information identified.

Decomposition temperature: No information identified.

Viscosity: No information identified.

10. Stability and Reactivity

Reactivity: No information identified.

Chemical Stability: Stable under ordinary conditions of use and storage.

Possibility of Hazardous reactions: Heating to decomposition or contact with acids can liberate poisonous cyanide gas/vapors (applies to Guanidinium thiocyanate). For all other ingredients, no potential for hazardous reactions identified.

Conditions to Avoid: Heat, contact with acids liberates very toxic gas

Incompatible Materials: Acids, oxidizing agents.

Hazardous Decomposition Products: Carbon oxides, sodium oxides, hydrogen cyanide

Hazardous Polymerization: Will not occur.

11. Toxicological Information

Acute Toxicity: Guanidinium thiocyanate has an acute oral LD50 of 593 mg/kg.

Irritation/Sensitization: No data identified on ingredients.

Repeated dose toxicity – No data identified on ingredients.

Reproductive (fertility) and Developmental (birth defects) toxicity – No data identified. None of the ingredients are considered reproductive or developmental toxicants.

Mutagenicity and Carcinogenicity – No data identified on mutagenicity. None of the ingredients are listed by NTP, IARC or OSHA as carcinogens.

Material Safety Data Sheet*Effective Date: November 23rd, 2011**Supersedes: Not applicable*

CT / NG Assay

12. Ecological Information**Ecotoxicity:** Guanidinium thiocyanate may cause long lasting harmful effects to aquatic life.**Persistence and degradability:** No data identified.**Bioaccumulative potential:** No data identified.**Mobility in soil:** No data identified.**Other adverse effects:** No data identified.

13. Disposal Considerations

Biological specimens, including used cartridges, should be treated as capable of transmitting infectious agents. Consult your institution's environmental waste personnel on proper disposal of used cartridges and unused reagents. This material may exhibit characteristics of federal EPA Resource Conservation and Recovery Act (RCRA) hazardous waste requiring specific disposal requirements. Check state and local regulations as they may differ from federal disposal regulations. Institutions outside the USA should check their country hazardous waste disposal requirements.

14. Transport Information

Transport in accordance with all federal, state, and local transportation regulations.

All components are not dangerous goods as regulated by US DOT, IMDG, or IATA.

15. Regulatory Information**Safety, health and environmental regulations/legislation specific for the substance or mixture**

This SDS complies with the requirements under US, EU and GHS (EU CLP - Regulation EC No 1272/2008) guidelines. Labeling information under CLP including signal word and hazard/precautionary statements are included in this SDS. Exemptions for including some of this information on product label are pursuant to CLP Article 1(5)(d) and 29 CFR 1910.1200 (g)(2)(i)(C)(1)&(2).

OSHA Hazardous

Lysis Reagent: Heating to decomposition or contact with acids can liberate poisonous cyanide gas/vapors



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National Fire Protection Lysis and Binding Reagents:

Agency (NFPA) Rating Health – 2 (Lysis Reagent)
Flammability – 1 (Binding reagent)
Reactivity - 0

WHMIS classification This product is not controlled under WHMIS.

TSCA status For R&D consumers, products are to be used only for R&D purposes.

SARA section 313 Not listed.

California proposition 65 Not listed.

Product label

WARNING

Contains Guanidinium thiocyanate. Contact with acids liberates very toxic gas. Wash hands thoroughly after handling. Wear protective gloves and eye protection.

IF ON SKIN: Wash with plenty of soap and water.

IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

If skin or eye irritation occurs: Get medical advice/attention.

IF SWALLOWED: Rinse mouth. Call a POISON CENTER / physician if you feel unwell.

Avoid release to the environment; may cause long lasting harmful effects to aquatic life. Dispose of contents/container in accordance with local and regional / national/ international regulations.

Consult Safety Data Sheet for other precautionary statements.



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16. Other Information

Disclaimer: The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties, protections and disposal which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.