

Material Safety Data Sheet

Effective Date: March 15th, 2012

Supersedes: May 25th, 2011

Xpert HemosIL® FII & FV

1. Product and Company Identification

1.1 Identification of the product

Product Name: Xpert HemosIL® FII & FV

Product Number: GXHEMOSIL-10

1.2 Company identification:

MANUFACTURER:

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089-1189 (USA)
Tel. +1 408 541 4191
Fax +1 408 541 4192

DISTRIBUTOR EU:

Via Roma, 103
20040 Cavenago Brianza (Italy)

DISTRIBUTOR US/CANADA:

Beckman Coulter Inc.
250 S. Kraemer Blvd.
Brea, CA 92821, U.S.A

E-mail address of the competent person: infosds@mail.ilww.it

1.3 Emergency phone: +44 (0)3700 492 795
+1 215 207 0061 (USA and Canada)

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 four (4) components, some of which are in freeze-dried powders and reagents which are contained in the cartridge. 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 Reagent #2 containing guanidinium hydrochloride

Classification of the substance or mixture: Acute toxicity, oral (Category 5)
Skin irritation (Category 2)
Regulation (EC) 1272/2008 [GHS] Eye irritation (Category 2A)

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Label Elements (See section 15 of this SDS)

CLP/GHS hazard pictogram



CLP/GHS signal word **Warning**

CLP/GHS Hazard and Precautionary statements

H303 – Maybe harmful if swallowed. H315 – Causes skin irritation. H319 – Causes serious eye irritation.

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. P301 - IF SWALLOWED: Rinse mouth. Call a POISON CENTER / physician if you feel unwell. P501 - Dispose of contents/container to location in accordance with local and regional/national/international regulations.

US Hazard Overview Reagent #2 contains guanidinium hydrochloride and Tween-20

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 two (2) beads to which two (2) aqueous reagents are added as part of an assay.

The following classifications (EU Risk phrases and CLP/GHS H-phrases) apply to Reagent #2.

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Reagent #2 is a clear, colorless liquid with the following hazardous ingredients:

Ingredient	CAS#	EINECs / ELINCS #	% Composition	EU Risk Phrase	CLP/GHS Classification
Tween-20 [polyoxyethylene sorbitan monolaurate]	9005-64-5	unlisted	< 5	R38	H316
Guanidinium hydrochloride	50-01-1	200-002-3	< 20	R22, R36, R38	H303, H315, H319

Reagent #1 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:** Causes serious eye irritation. Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Consult a physician.
- Skin:** Causes 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, nitrogen oxides, hydrogen chloride gas.

Flammability/Explosivity: None expected.

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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 in accordance with local and regional/national/international regulations. (see Section 13).

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 hydrochloride 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).

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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 – 8.5 (liquid reagents)

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

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

Flash point: No information identified.

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.

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: No information identified.

Conditions to Avoid: Keep away from heat

Incompatible Materials: Strong oxidizing agents.

Hazardous Decomposition Products (fire): Carbon & sodium oxides, hydrogen chloride gas

Hazardous Polymerization: Will not occur.

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11. Toxicological Information

Acute Toxicity: Guanidinium hydrochloride has an acute oral LD₅₀ of 475 mg/kg (rat).

Irritation/Sensitization: Skin – rabbit – Skin irritation; Eyes – rabbit – Eye irritation

Repeated dose toxicity: No information identified.

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.

12. Ecological Information

Ecotoxicity: Guanidinium hydrochloride not classified as either acute or chronic aquatic toxicity.

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.

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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 Guanidinium hydrochloride: Toxic by ingestion, Irritant

National Fire Protection Agency (NFPA) Rating Guanidinium hydrochloride:
 Health – 2
 Flammability – 0
 Reactivity - 0

WHMIS classification This product is not classified 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 Not listed.

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Product label



WARNING

Contains guanidinium hydrochloride. 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.

Dispose of contents/container in accordance with local and regional / national/ international regulations.

Consult Safety Data Sheet for other precautionary statements.

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.