Safety Data Sheet

SECTION 1: Identification

1.1. Product Identifier
ClearGuard® HD Antimicrobial Barrier Cap

1.2. Product Identification Number
CGHD-100, CGHD-400

1.3. Recommended Use
The ClearGuard HD is indicated for use as an end cap for use with hemodialysis catheter hubs.

1.4. Supplier's Details

1.4.1.	**MANUFACTURER:**	Pursuit Vascular, Inc.
1.4.2.	**ADDRESS:**	6901 East Fish Lake Road Suite 166 Maple Grove, MN 55369-5456, USA
1.4.3.	**TELEPHONE:**	612-424-9006

SECTION 2: Hazard Identification

2.1. Hazard Classification
- **2.1.1.** GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)
- **2.1.2.** Acute toxicity, Oral (Category 4), H302
- **2.1.3.** Acute aquatic toxicity (Category 1), H400
- **2.1.4.** Chronic aquatic toxicity (Category 1), H410
- **2.1.5.** **NOTE:** For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2. Label Elements

2.2.1. Pictograms

2.2.2. Signal Word
- 2.2.2.1. Caution
- 2.2.2.2. Warning

2.2.3. Hazard Statement(s)

2.2.3.1.	H302	Harmful if swallowed.
2.2.3.2.	H319	Causes serious eye irritation.
2.2.3.3.	H410	Very toxic to aquatic life with long lasting effects.

2.2.4. Precautionary Statement(s)

2.2.4.1.	P264	Wash skin thoroughly after handling.
2.2.4.2.	P273	Avoid release to the environment.
2.2.4.3.	P301 + P312 + P330	IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth.
2.2.4.4.	P391	Collect Spillage
2.2.4.5.	P501	Dispose of contents/ container to an approved waste disposal plant.

2.2.5. Hazards Not Otherwise Classified (HNOC) or Not Covered by GHS

2.2.5.1. If small particles are generated during further processing, handling, or by other means, combustible dust concentrations in the air may form.

2.2.5.2. Dust may cause irritation due to abrasion. Repeated or prolonged skin contact may cause reddening, itching, and inflammation.

2.2.5.3. Dusts may cause mechanical irritation including pain, lacrimation, and redness. Effects may become more serious with repeated or prolonged contact.

SECTION 3: Composition/Information on Ingredients

Ingredient	C.A.S. Number	% by Weight
Chlorhexidine Di(acetate)	56-95-1	< 1%
Ethylene-Polypropylene Polymer Shield/Plug	Mixture	25 - 35%
Polyamide Glass-Reinforced Nylon Resin Lock Rings	Mixture	20 - 30%
PET/LDPE/Foil/Co-Extrusion/LLDPE Pouch	Mixture	25 - 35%
Colorants	Mixture	< 1%

3.1. Hazardous Substances

3.1.1.	Ingredient Name	Chlorhexidine Di(acetate)
3.1.2.	Chemical Name	1,1'-hexamethylene bis-[5-(4-chlorophenyl)biguanide]diacetate
3.1.3.	Molecular Formula	$C_{22}H_{30}Cl_2N_{10} \cdot 2C_2H_4O_2$
3.1.4.	Molecular Weight	625.55 g/mol
3.1.5.	C.A.S. Number	56-95-1
3.1.6.	EC Number	200-302-4

SECTION 4: First Aid Measures

4.1. Description of First Aid Measures

4.1.1. General Advice

4.1.1.1. Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

4.1.2. If Inhaled

4.1.2.1. If breathed in, move person into fresh air.

4.1.2.2. If not breathing, give artificial respiration.

4.1.2.3. If breathing is difficult, ensure airway is clear and give oxygen. If heart has stopped, immediately begin cardiopulmonary resuscitation (CPR).

4.1.2.4. Keep affected person warm and at rest.

4.1.2.5. GET IMMEDIATE MEDICAL ATTENTION.

4.1.3. In Case of Skin Contact

4.1.3.1. Immediately wash skin with plenty of soap and water while removing contaminated clothing and shoes.

4.1.3.2. Get medical attention if irritation develops or persists.

4.1.4. In Case of Eye Contact

4.1.4.1. Flush immediately with large amounts of water for at least 15 minutes. Eyelids should be held away from the eyeball to ensure thorough rinsing.

4.1.4.2. Get medical attention if irritation persists.

4.1.5. If Swallowed

4.1.5.1. If spontaneous vomiting occurs, keep head below hips to prevent aspiration and monitor for breathing difficulty.

4.1.5.2. Never give anything by mouth to an unconscious person.

4.1.5.3. Keep affected person warm and at rest.

4.1.5.4. GET IMMEDIATE MEDICAL ATTENTION.

4.1.6. NOTES TO PHYSICIAN

4.1.6.1. Treat symptomatically with supportive therapy.

4.2. Most Important Symptoms and Effects, both Acute and Delayed

4.2.1. Severe irritant to the eye.

4.2.2. Accidental ingestion is likely to result in irritation of the gastrointestinal tract.

4.3 Indication of any Immediate Medical Attention and Special Treatment Needed

4.3.1. No Data Available

SECTION 5: Fire-Fighting Measures

5.1. Suitable Extinguishing Media

5.1.1. Use water spray, alcohol-resistant foam, dry chemical, carbon dioxide, or fire-fighting foam for Class B fires to extinguish fire.

5.2. Special Hazards Arising from the Substance or Mixture

5.2.1. A variety of decomposition products may occur including simple hydrocarbons to toxic and irritating gases such as carbon, carbon monoxide, carbon dioxide, nitrogen oxides (NOx), hydrogen chloride gas, acids, ketones, and aldehydes.

5.3. Advice for Firefighters

5.3.1. Material will burn in a fire.

5.3.2. Large molten masses may ignite spontaneously in air. Water quenching is a good practice.

5.3.3. Evacuate area and fight fire both upwind and from a safe distance.

5.3.4. Use water spray to cool adjacent structures and to protect personnel.

5.3.5. Dike fire control water for later disposal.

5.3.6. Firefighters must wear NIOSH approved positive pressure breathing apparatus (SCBA) with full face mask and full protective equipment.

5.4. Further Information

5.4.1. Hazardous melting and dripping may occur at elevated temperatures.

5.4.2. May burn at or above flash point, and airborne dust may explode if ignited.

5.4.3. Flash Point > 650 °F (> 343.3 °C) (PMCC)

SECTION 6: Accidental Release Measures

6.1. Personal Precautions, Protective Equipment, and Emergency Procedures

6.1.1. Use personal protective equipment. See section 8.

6.2. Environmental Precautions

6.2.1. Prevent further leakage or spillage if safe to do so.

6.2.2. Do not let product enter drains.

6.2.3. Discharge into the environment must be avoided.

6.2.4. Take immediate steps to stop and contain release.

6.2.5. Notify local authorities and the National Response Center, if required.

6.3. Methods and Materials for Containment and Cleaning Up

6.3.1. Mechanically collect and arrange for proper disposal.

6.3.2. Keep in suitable, closed containers for disposal.

6.4. Reference to Other Sections

6.4.1. Dispose of according to Section 13.

SECTION 7: Handling and Storage

7.1. Precautions for Safe Handling

7.1.1. Avoid contact with eyes.

7.1.2. Wash hands and exposed skin after use.

7.1.3. Contaminated clothing should be thoroughly cleaned.

7.2. Conditions for Safe Storage, including any Incompatibilities

7.2.1. Keep disposal container tightly closed.

7.2.2. Keep in a dry place.

7.2.3. Storage class (TRGS 510): Non Combustible Solids

7.3. Specific End Use(s)

7.3.1. Apart from the uses mentioned in Section 1.3 no other specific uses are indicated.

SECTION 8: Exposure Controls / Personal Protection

8.1. Control Parameters

8.1.1. Occupational Exposure Limits

8.1.1.1. Contains no substances with occupational exposure limit values.

8.2. Exposure Controls

8.2.1. Engineering Controls

8.2.1.1. Handle in accordance with good industrial hygiene and safety practices.

8.2.1.2. Wash hands before and after each use.

8.3. Personal Protective Equipment (PPE)

8.3.1. Eye/Face Protection

8.3.1.1. Keep away from eyes.

8.3.1.2. Safety glasses with side-shields conforming to EN166 are recommended.

8.3.1.3. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

8.3.1.4. Have eye washing facilities readily available where eye contact can occur.

8.3.2. Skin Protection

8.3.2.1. Handle with gloves.

8.3.2.2. Gloves should be inspected prior to use.

8.3.2.3. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product.

8.3.2.4. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

8.3.2.5. Wash and dry hands.

8.3.3. Body Protection

8.3.3.1. No body protection is required.

8.3.4. Respiratory Protection

8.3.4.1. For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator.

8.3.4.2. For higher level protection use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirator cartridges.

8.3.4.3. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

SECTION 9: Physical and Chemical Properties

9.1. Information on Basic Physical and Chemical Properties

Physical /Chemical Description	ClearGuard HD Antimicrobial Barrier Cap
Form	Crystallized Solid (Chlorhexidine) Solid (Plug/Shield/Lock Rings)
Chemical Family	Antimicrobial (Chlorhexidine Di(acetate)) Polypropylene Copolymer (Plug/Shield) Polyamide Glass-Reinforced Nylon Resin (Lock Rings)
Color	White/Off-White (Plug/Shield) Red/Blue (Lock Rings)
Odor	Odorless
Odor Threshold (ppm)	No Data
pH (Value)	Not Applicable
Specific Gravity	Not Applicable
Melting Point (°C)	143.3 – 200°C (290 - 392°F)
Boiling Point (°C)	Not Applicable
Flash Point (°C)	> 343.3°C (> 650°F) (PMCC)
Freezing Point (°C)	Not Available
Flammability (Solid, Gas)	May form combustible dust concentrations in air during disposal processing.
Vapor Pressure (mm Hg)	Not Applicable
Evaporation Rate	Not Applicable
Vapor Density (Air = 1)	Not Applicable
Volatile Organic	Not Available
Percent Volatile	Not Available
Pour Point	Not Available
Density (g/mL)	0.895 - 1.000 g/mL (25°C)
Solubility (Water)	Not Applicable
Solubility (Other)	Not Applicable
Octanol / Water Partition	Not Applicable
Decomposition Temperature (°C)	Not Available
Partition Coefficient	Not Applicable
Auto Ignition Temperature (°C)	Not Applicable
Decompression Temperature (°C)	Not Applicable
Viscosity (mPa.s)	Not Applicable
Explosive Properties	Not Applicable
Upper Explosion Limit	Not Applicable
Lower Explosion Limit	Not Applicable
Oxidizing Properties	Not Applicable
Additional Information	None

SECTION 10: Stability and Reactivity

10.2. Reactivity

10.2.1. Due to the cationic character of Chlorhexidine salts, they are chemically incompatible with anionic compounds.

10.2.2. Keep away from sulfates, borates, bicarbonates, and chlorides.

10.3. Chemical Stability

10.3.1. Avoid contact with strong oxidizers.

10.3.2. Avoid high temperatures, open flames, sparks, and the use of ungrounded electrical equipment.

10.3.3. See precautions listed under Handling & Storage in Section 7.

10.4. Hazardous Reactions

10.4.1. Combustion may produce hazardous combustion products and other decomposition products in the case of incomplete combustion.

10.5. Conditions to Avoid

10.5.1. Keep away from heat, sources of ignition, and direct sunlight.

10.5.2. Keep away from moisture.

10.6. Incompatible Materials

10.6.1. Keep away from strong acids, strong bases, and oxidizing agents.

10.6.2. Chemically incompatible with anionic compounds.

10.7. Hazardous Decomposition Product(s)

10.7.1. In the event of fire, see Section 5.

10.7.2. Combustion may produce hazardous combustion products and other decomposition products in the case of incomplete combustion.

10.7.3. Combustion or thermal decomposition will evolve toxic vapors.

10.7.4. In fire conditions or when heated to decomposition, this product emits toxic fumes of Cox, NOx, ammonia, chlorine-derivatives, and small amounts of p-chloroaniline.

10.8. Hazardous Polymerization

10.8.1. Will not occur.

SECTION 11: Toxicological Information

NOTE: The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. In addition, toxicological data on ingredients may not be reflected in the material classification and/or the signs and symptoms of exposure, because an ingredient may be present below the threshold for labeling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.

11.1. Information on toxicological effects

11.1.1. Acute Toxicity

11.1.1.1. **LD50 Oral**

11.1.1.1.1. Mouse/Rat - 2,000 mg/kg

11.1.1.1.2. Accidental ingestion may cause human health damage. It is likely to result in irritation of the gastrointestinal tract.

11.1.1.2. **Inhalation**

11.1.1.2.1. Chlorhexidine may have inhalation toxicity.

11.1.1.2.2. Polypropylene dust may be irritation to the respiratory system.

11.1.1.2.2.1. Prolonged and repeated inhalation of dust may cause impaired lung function and lung changes.

11.1.1.2.2.2. Vapors and fumes from thermal processing may be irritating to the eyes and respiratory system.

11.1.1.3. **Skin**

11.1.1.3.1. (Chlorhexidine) Rabbit (500 mg/24h); Mild Irritation

11.1.1.3.1.1. Some allergic reactions have been reported after skin contact.

11.1.1.3.1.2. Chlorhexidine is not expected to cause significant or prolonged irritation by skin contact.

11.1.1.3.1.3. Repeated exposure may cause dermal disturbances.

11.1.1.3.1.4. It is not expected to cause systemic harmful effects after skin contact.

11.1.1.3.2. Polypropylene based polymer exposure may cause adverse effects or damage to the following organs or organ systems: skin, eyes, and respiratory tract.

11.1.1.4. **Eye Contact**
11.1.1.4.1. Chlorhexidine is highly irritation to the eyes.
11.1.1.4.2. This material is considered to represent risk of serious damage to the eyes.

11.1.1.5. **Mutagenicity**
11.1.1.5.1. There is no evidence of mutagenic potential.

11.1.1.6. **Carcinogenicity**
11.1.1.6.1. In repeated dose studies, chlorhexidine was not carcinogenic and/or mutagenic in rats and mice.

11.1.1.7. **Reproductive Toxicity**
11.1.1.7.1. No evidence of fetal malformations or significant developmental toxicity.

11.1.1.8. **STOT-Single Exposure**
11.1.1.8.1. May cause irritation to the respiratory system.

11.1.1.9. **STOT-Repeated Exposure**
11.1.1.9.1. None Known

11.1.1.10. **Aspiration Hazard**
11.1.1.10.1. None Known

11.1.1.11. **IARC**
11.1.1.11.1. 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.

11.1.1.12. **ACGIH**
11.1.1.12.1. No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

11.1.1.13. **NTP**
11.1.1.13.1. 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.

11.1.1.14. **OSHA**
11.1.1.14.1. 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.

SECTION 12: Ecological Information

12.1. Ecotoxicological Information

12.1.1. Ecotoxicity

12.1.1.1. Acute Toxicity (Fish)	1.4 mg/l (Chlorhexidine)
12.1.1.2. Acute Toxicity (Daphnia magna)	Not Available
12.1.1.3. Acute Toxicity (Algae)	Not Available

12.1.2. Persistence / Biodegradation
12.1.2.1. Not readily biodegradable.

12.1.3. Bioaccumulation
12.1.3.1. Not classified in terms of bioaccumulation in aquatic organisms.

12.1.4. Mobility in Environment
12.1.4.1. Not classified in terms of mobility in air, soil and water.

12.1.5. Results of PBT and vPvB Assessment
12.1.5.1. Not classified as PBT or vPvB.

12.1.6. Other Effects

12.1.6.1. NOEC-value 1.0 mg/l (Chlorhexidine)

12.1.7. NOTE: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

SECTION 13: Disposal Considerations

13.1. Waste Disposal

13.1.1. Bury on an authorized landfill site or incinerate under approved controlled conditions, using incinerators suitable for the disposal of noxious chemical waste.

13.1.2. Disposal should be in accordance with local, state, or national legislation.

SECTION 14: Transport Information

14.1. Land Transport

14.1.1.	UN Number	3077
14.1.2.	D.O.T. Proper Shipping Name	Environmentally hazardous substances, solid, N.O.S. (Chlorhexidine Acetate)
14.1.3.	Transport Hazard Class(es)	9
14.1.4.	Packing Group	III
14.1.5.	EMS Number	F-A, S-F
14.1.6.	Hazard Label(s)	9
14.1.7.	Environmental Hazards	Yes; Marine Pollutant

14.2. Sea Transport

14.2.1.	UN Number	3077
14.2.2.	D.O.T. Proper Shipping Name	Environmentally hazardous substances, solid, N.O.S. (Chlorhexidine Acetate)
14.2.3.	Transport Hazard Class(es)	9
14.2.4.	Packing Group	III

14.3. Air Transport

14.3.1.	UN Number	3077
14.3.2.	D.O.T. Proper Shipping Name	Environmentally hazardous substances, solid, N.O.S. (Chlorhexidine Acetate)
14.3.3.	Transport Hazard Class(es)	9
14.3.4.	Packing Group	III
14.3.5.	Environmental Hazards	Yes

14.4. Further Information

14.4.1. EHS-Mark required (ADR 2.2.9.1.10, IMDG code 2.10.3) for single packagings and combination packagings containing inner packagings with Dangerous Goods > 5L for liquids or > 5kg for solids.

SECTION 15: Regulatory Information

15.1. US Federal Regulations

15.1.1. All ClearGuard HD cap materials are on the TSCA inventory, or are not required to be listed on the TSCA inventory.

15.1.2. The ClearGuard HD cap, as supplied, contains no hazardous substances regulated under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302), or any extremely hazardous substances regulated under the Emergency Planning and Community Right to Know Act (EPCRA) (40 CFR 355), and thus a release of this material as supplied has no reporting requirements under these regulations.

15.1.2.1. **SARA 302 Components**

15.1.2.1.1. No chemicals in the ClearGuard HD cap device are subject to the reporting requirements of SARA Title III, Section 302.

15.1.3. The ClearGuard HD cap does not contain toxic chemicals (in excess of the applicable de Minimis concentration) that are subject to the annual toxic chemical release reporting requirements of the Superfund Amendments and Reauthorization Act (SARA) Section 313 (40 CFR 372).

15.1.3.1. **SARA 313 Components**

15.1.3.1.1. The ClearGuard HD cap device 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.

15.1.3.2. **SARA 311/312 Hazards**

15.1.3.2.1. Acute Health Hazard

15.1.4. Check local, regional or state/provincial regulations for any additional requirements as these may be more restrictive than federal laws and regulations. Failure to report may result in substantial civil and criminal penalties.

15.2. State Regulations

15.2.1. Massachusetts Right To Know Components

15.2.1.1. No ClearGuard HD cap components are subject to the Massachusetts Right to Know Act.

15.2.2. Pennsylvania Right To Know Components

15.2.2.1. Chlorhexidine di(acetate) hydrate

15.2.2.1.1. CAS-No. 56-95-1 Revision Date 2009-07-17

15.2.3. New Jersey Right To Know Components

15.2.3.1. Chlorhexidine di(acetate) hydrate

15.2.3.1.1. CAS-No. 56-95-1 Revision Date 2009-07-17

15.2.4. California Prop. 65 Components

15.2.4.1. The ClearGuard HD cap device does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

15.3. International Regulations

15.3.1. All ingredients are on the following chemical inventories or are not required to be listed:

15.3.1.1. US INVENTORY (TSCA)

15.3.1.2. EU INVENTORY (EINECS/ELINCS)

15.3.1.3. KOREA INVENTORY (ECL)

15.3.1.4. CHINA INVENTORY (IECS)

SECTION 16: Other Information

16.1. HMIS Rating

16.1.1.	Health Hazard	1
16.1.2.	Chronic Health Hazard	0
16.1.3.	Flammability	1
16.1.4.	Physical Hazard	0

16.2. NFPA Rating

16.2.1.	Health Hazard	2
16.2.2.	Fire Hazard (Flammability)	3
16.2.3.	Reactivity Hazard (Instability)	0
16.2.4.	Special Hazards:	None

16.2.5. **NOTE:** National Fire Protection Association (NFPA) hazard ratings are design for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

16.3. Disclaimer

16.3.1. The information in this Safety Data Sheet (SDS) is believed to be correct as of the date issued. Pursuit Vascular, Inc. makes no warranties, expressed or implied, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose or course of performance of usage of trade. The end user is responsible for determining whether the ClearGuard HD cap is suitable for the application as a particular purpose and suitable for use an end cap for use with hemodialysis catheter hubs. Given the variety of factors that can affect the use and application of a ClearGuard HD device, some of which are uniquely within the user's knowledge and control, it is essential that the user evaluate the ClearGuard HD cap to determine whether it is fit for a particular purpose and suitable for user's method of use or application.

16.3.2. Pursuit Vascular, Inc. provides information in electronic form as a service to its customers. Due to the remote possibility that electronic transfer may have resulted in errors, omissions or alterations in this information, Pursuit Vascular, Inc. makes no representations as to its completeness or accuracy. In addition, information obtained from a database may not be as current as the information in the SDS available directly from Pursuit Vascular, Inc.

16.3.3.