Chemo/Hazardous Drug Clean

HDCLEAN
HAZARDOUS DRUG CLEAN

For Daily Removal of Hazardous Drug Surface Contamination in Preparation and Administration Areas

Hazardous Drug Clean (HDClean™) is an easy two step wiping procedure using towelettes that effectively removes hazardous drug surface contamination. HDClean™ has been tested to remove surface contamination of docetaxel, paclitaxel, 5-flourouracil, cyclophosphamide, ifosfamide, and cisplatin.

HDCleanTM Advantage:

- **Simple towelette wiping procedure**
- **Proven effective in laboratory tests**
- **Effective on a wide variety of hazardous drugs**
- **No residue left on surfaces after use**
- **No overpowering odor**
- **Larger towelettes offer expanded cleaning area up to 4 square feet**

Recommended Use: HDClean™ is recommended for cleaning hazardous drug storage, preparation, and administration areas before shift changes, at the end of the day, and after hazardous drug spill clean-up.

Directions for Use: HDClean™ is a two step wiping process. Use the towelette marked "1" to thoroughly wipe one area. Wipe the same area using the towelette marked "2". Open up a second pack of towelettes and repeat wiping of the same area with towelette marked "1" and then "2". Repeat this procedure for each 2 ft x 2 ft area wiped. DO NOT REUSE THE TOWELETTES. Discard towelettes in chemotherapy waste bin.

Approved for use on the following surfaces: chemical resistant laminate, phenolic resin, epoxy resin, high-density polyethylene, 316 stainless steel, 304 stainless steel, 201 stainless steel. **Use with caution on other surfaces**.

Caution: For external use only. Towelette chemistry can be harmful to eyes. Immediately flush eyes with plenty of water for 15 minutes after contact. If irritation persists, call a physician. Use in a ventilated area. May cause skin irritation. **FLAMMABLE: Keep away from fire or open flame.**

Active Ingredients: Quaternary ammonium and isopropyl alcohol.

Introduction

- Health care workers are exposed to hazardous drugs as a part of the dispensing and administration of medications
- Evaluation of pharmacy and nursing employees have documented the presence of hazardous drugs on both the surface of their work area and in their urine
- Studies have also been conducted that have detected the presence of chemotherapy on the outside of drug vials
- Surface wipe studies are recommended to be completed regularly in areas that prepare and administer hazardous drugs in order to understand the risk of exposure to employees
- ChemoGLO™ isawipekitthathasbeenusedinover 400 hospitals over the past 4 years
- Surface contamination for 5-FU, cyclophosphamide, ifosfamide, docetaxel, paclitaxel, and cisplatin are reported following use of the wipe kit
- As much as 80–90% of hospitals wiped have documented surface contamination of hazardous drugs, even when using all of the recommended best practices
- Because of the concerns associated with documented hazardous drug residue, HDClean™ was developed as a method to remove all detectable surface contamination
- HDClean™ utilizes a two-step system with specialized cleaning solutions and towelettes to remove hazardous drug residue from surfaces

Objectives

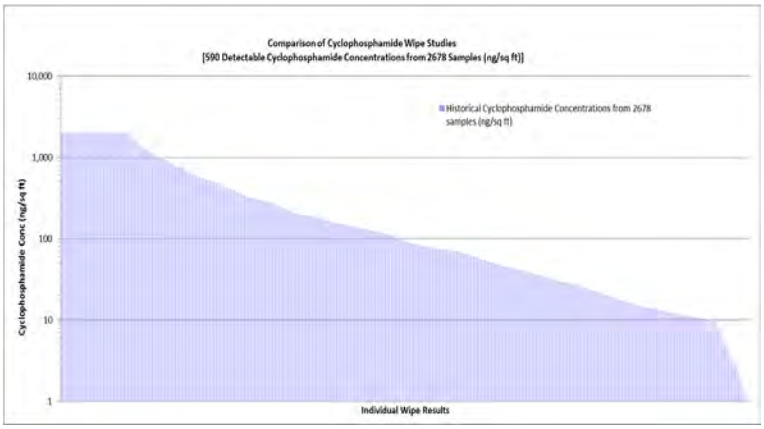
- To evaluate the effectiveness of HDClean™ in removing 5-FU, cyclophosphamide, ifosfamide, docetaxel, paclitaxel and cisplatin

Methods

- A total of 14 separate areas were contaminated with 5-FU, cyclophosphamide, ifosfamide, docetaxel, paclitaxel and cisplatin
- Each area was 2 ft x 2 ft (4 ft^2)
- Exposure of each drug on the 4 ft^2 site was 1,000 ng/ml
- Seven areas were cleaned with HDClean™ prior to sampling
  - Towelette #1 was used first to clean the area and then followed by towelette #2
  - Procedure was repeated a second time on each contaminated area
- ChemoGLO™ wipe methods and liquid chromatography tandem-mass spectrometry (LC-MS/MS) assay for 5-FU, cyclophosphamide, ifosfamide, docetaxel, and paclitaxel, and inductively coupled plasma mass spectrometry (ICP-MS) assay for cisplatin were used for analysis

Results

- ChemoGLO™ experience for surface contamination risks with cyclophosphamide
  - 3.4% of samples: detectable surface concentration > 1 ng/cm^2
  - 7.7% of samples: detectable surface concentration 0.1-1 ng/cm^2
  - 88.9% of samples: detectable surface concentration < 0.1 ng/cm^2



- Bench top surfaces were contaminated with 6 different chemotherapy agents (5-FU, cyclophosphamide, ifosfamide, docetaxel, paclitaxel and cisplatin) at a concentration of 1,000 ng/ml
- Seven of the areas were wiped using HDClean™ (two-towelette system, repeated once) and 7 were not wiped
- ChemoGLO™ wipe kit was used to detect residual surface contamination of the hazardous drugs

	Total number of tests	ChemoGLO™ measured concentrations of each drug
Samples not using HDClean™	7	900 – 1,000 ng/ml
Samples using HDClean™	7	Non-detectable

- LC-MS/MS assays for 5-FU, cyclophosphamide, ifosfamide, docetaxel, and paclitaxel had a lower limit of quantification for each drug of 10 ng/mL.
- ICP-MS assay had a lower limit of quantification for cisplatin of 1 ng/mL

Conclusions

- Surface contamination in hospitals continues to be detectable, even when all best practices are being utilized
- Health care employee risk can be evaluated with regular surface contamination monitoring
- Additional strategies and products need to be developed to minimize surface contamination of hazardous drugs and subsequent employee risk
- HDClean™, when used according to product recommendations, demonstrated removal of all detectable surface contamination of the following chemotherapy drugs: 5-FU, cyclophosphamide, ifosfamide, docetaxel, paclitaxel, and cisplatin at exposures that have been reported in hospitals and pharmacies.

1 University of North Carolina (UNC) Eshelman School of Pharmacy
2 UNC Lineberger Comprehensive Cancer Center
3 UNC Institute for Pharmacogenomics and Individualized Therapy,
4 Carolina Center of Cancer Nanotechnology Excellence, University of North Carolina, Chapel Hill, NC 5 ChemoGLO, LLC, Chapel Hill, NC
6 University of North Carolina Hospitals

Evaluation of Hazardous Drug Clean™ (HDClean™), a two-step towelette system, in removing surface contamination of hazardous drugs

Stephen F. Eckel[1,5,6], William F. McAdoo[1,2], Candice A. Sherwood[1,2], Sara K. O'Neal,[1,2] and William C. Zamboni[1,2,3,4,5]

Material Safety Data Sheet
May be used to comply with OSHA's Hazard Communication Standard, 29 CFR 1910 1200. Standard must be consulted for specific requirements.

U.S. Department of Labor
Occupational Safety and Health Administration (Non-Mandatory Form)
Form Approved
OMB No. 1218-0072

IDENTITY *(as Used on Label and List)*
HDClean 1

Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that.

Section I

Manufacturer's name ChemoGLO, LLC	Emergency Telephone Number (919) 428-6759
Address *(Number, Street, City, State and ZIP Code)*	Telephone Number for Information (919) 428-6759
96 Mountain Laurel	Date Prepared 11/28/2012
Chapel Hill, NC 27517	Signature of Preparer *(optional)*

Section II—Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity, Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Octyl decyl dimethyl Ammonium chloride (32426.11-2)	N/A	N/A	N/A	0.025
Dioctyl dimethyl Ammonium chloride (5538-94-3)	N/A	N/A	N/A	0.010
Didecyl dimethyl Ammonium chloride (7173-51-5)	N/A	N/A	N/A	0.015
Alkyl (ci2, 40%; Cic, 10%) dimethyl benzyl ammonium chloride (68424-85-1)	N/A	N/A	N/A	0.034

Section III—Physical/Chemical Characteristics

Boiling Point	N/A	Specific Gravity (H_20 = 1)	N/A
Vapor Pressure (mm Hg)	N/A	Melting Point	N/A
Vapor Density (AIR = 1)	Unknown	Evaporation Rate (Butyl Acetate = 1)	Same as Water

Solubility in Water Complete

Appearance and Odor Foil packaged moist towelette, pleasant odor

Section IV—Fire and Explosion Hazard Data

Flash Point (Method Used) N/A	Flammable Limits N/A	LEL N/A	UEL N/A

Extinguishing Media Co2 – Dry Chemical – Foam – Water Spray

Special Fire Fighting Procedures Co2 – Dry Chemical – Foam – Water Spray

Unusual Fire and Explosion Hazards None Known

(Reproduce locally) 1985 OSHA 174 Sept.

Section V—Reactivity Data

Stability	Unstable		Conditions to Avoid N/A
	Stable	X	

Incompatibility *(Materials to Avoid)* N/A

Hazardous Decomposition or Byproducts: Carbon monoxide and other unidentified organic gases may occur during in complete combustion.

Hazardous Polymerization	May Occur		Conditions to Avoid N/A
	Will Not Occur	X	

Section VI—Health Hazard Data

Route(s) of Entry: Eye | Inhalation? N/A | Skin? X | Ingestion? X

Health Hazards *(Acute and Chronic)*: Eye: redness, possible eye damage. Skin: redness, possible skin irritation.

Swallowing: probable mucosal damage.

Carcinogenicity: None Known | NTP? N/A | IARC Monographs? N/A | OSHA Regulated? N/A

Signs and Symptoms of Exposure: None Known

Medical Conditions Generally Aggravated by Exposure: None Known

Emergency and First Aid Procedures: Eye contact: flush immediately with water for 15 minutes. Call a physician.

Skin: if irritation develops, immediately stop using product and wash with water for 15 minutes. If irritation persists call a physician. Ingestion: drink milk, egg whites, or gelatin solution. If these products are not available drink large quantities of water and call a physician.

Section VII—Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled: N/A

Waste Disposal Method: Dispose of used towelettes in chemotherapy waste bin.

Precautions to Be Taken in Handling and Storing: Handling: N/A. Storage: Keep away from heat or flame.

Other Precautions: Keep away from children.

Section VII—Control Measures

Respiratory Protection *(Specify Type)*: N/A

Ventilation	Local Exhaust N/A	Special	N/A
	Mechanical *(General)* N/A	Other	N/A

Protective Gloves: N/A | Eye Protection: N/A

Other Protective Clothing or Equipment: N/A

Work/Hygienic Practices: Wash hands after using towelettes.

Material Safety Data Sheet
May be used to comply with OSHA's Hazard Communication Standard, 29 CFR 1910 1200. Standard must be consulted for specific requirements.

U.S. Department of Labor
Occupational Safety and Health Administration (Non-Mandatory Form)
Form Approved
OMB No. 1218-0072

IDENTITY *(as Used on Label and List)* HDClean 2	*Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that.*

Section I

Manufacturer's name ChemoGLO, LLC	Emergency Telephone Number (919) 428-6759
Address *(Number, Street, City, State and ZIP Code)*	Telephone Number for Information (919) 428-6759
96 Mountain Laurel	Date Prepared 11/28/2012
Chapel Hill, NC 27517	Signature of Preparer *(optional)*

Section II—Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity, Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
2-propanol 67-63-0	(Vacated) TWA: 400 ppm (Vacated) TWA: 980 mg/m3 (Vacated) STEL: 500 ppm (Vacated) STEL: 1225 mg/m3 TWA: 400 ppm TWA: 980 mg/m3	TWA: 200 ppm STEL: 400 ppm	NIOSH IDLH 2000 ppm	50-100%

Section III—Physical/Chemical Characteristics

Boiling Point	82.3C	Specific Gravity (H_20 = 1)	0.786-0.788
Vapor Pressure (mm Hg)	33 mg Hg at 20C	Melting Point	-88C
Vapor Density (AIR = 1)	2.07	Evaporation Rate (Butyl Acetate = 1)	1.5

Solubility in Water Miscible

Appearance and Odor Foil packaged moist towelette, alcohol odor

Section IV—Fire and Explosion Hazard Data

Flash Point (Method Used)	35C	Flammable Limits	LEL 2%	UEL 12%

Extinguishing Media Co2 – Dry Chemical – Alcohol Resistant Foam – Dry Sand

Special Fire Fighting Procedures Co2 – Dry Chemical – Alcohol Resistant Foam – Dry Sand

Unusual Fire and Explosion Hazards Risk of ignition

(Reproduce locally) 1985 OSHA 174 Sept.

Section V—Reactivity Data

Stability	Unstable		Conditions to Avoid: Heat, flame, sparks
	Stable	X	

Incompatibility *(Materials to Avoid)*: Strong oxidizing agents, acids, halogens, acid anhydrides

Hazardous Polymerization	May Occur		Conditions to Avoid: N/A
	Will Not Occur	X	

Section VI—Health Hazard Data

Route(s) of Entry: Eye | Inhalation? X | Skin? X | Ingestion? X

Health Hazards *(Acute and Chronic)*: Eye: redness, possible eye damage. Skin: redness, possible skin irritation.

Inhalation: possible irritation of respiratory tract. Swallowing: probable mucosal damage.

Carcinogenicity: None Known | NTP? N/A | IARC Monographs? N/A | OSHA Regulated? N/A

Signs and Symptoms of Exposure: Inhalation: drowsiness/dizziness. Ingestion: nausea, vomiting

Medical Conditions Generally Aggravated by Exposure: None Known

Emergency and First Aid Procedures: Eye contact: flush immediately with water for 15 minutes. Call a physician.

Skin: if irritation develops, immediately stop using product and wash with water for 15 minutes. If irritation persists call a physician. Ingestion: do not induce vomiting. Call a physician. Inhalation: move away from product to a well ventilated area.

Section VII—Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled: N/A

Waste Disposal Method: Dispose of used towelettes in chemotherapy waste bin.

Precautions to Be Taken in Handling and Storing: Handling: N/A. Storage: Store in a cool, dry space. Keep away from heat or flame.

Other Precautions: Keep away from children.

Section VII—Control Measures

Respiratory Protection *(Specify Type)*: N/A

Ventilation	Local Exhaust: N/A	Special: N/A
	Mechanical *(General)*: N/A	Other: Use in a well ventilated area

Protective Gloves: N/A | Eye Protection: N/A

Other Protective Clothing or Equipment: N/A

Work/Hygienic Practices: Wash hands after using towelettes.