



DATE: 8/28/97

FROM: JOSEPH IDUINO

- Corporate Headquarters: Two Annabel Lane, Suite 220, San Ramon, CA 94583 Fax (510) 327-7347 Voice (510) 327-0200
- Clinical R&D : 3158 Des Plaines Avenue, Suite 10-14, Des Plaines, IL 60018 Fax: (847) 803-9341 Voice: (847) 803-9330
- Sales & Marketing: 1719 Route 10, Suite 310 Parsippany, NJ 07054 Fax: (201) 359-0313 Voice: (201) 359-0800

FAX TO: MR. M. LOGAN

COMPANY: ALAMEDA COUNTY HEALTH DEPARTMENT

FAX #: (510) 337-9335

PAGES (INCLUDING THIS SHEET): 15

HARD COPY TO FOLLOW: YES NO

COMMENTS :

NOTICE OF CONFIDENTIALITY

Information contained in this facsimile transmittal is privileged and confidential information of the addressee and intended for the use of the intended recipient. If you are neither the intended recipient nor the employee or agent responsible for delivering this message to the intended recipient, you are hereby notified that any disclosure, copying, distribution or the taking of any action in reliance on the contents of this transmittal is strictly prohibited. If you have received this telecopy in error, please immediately notify us by telephone (510) 327-0200 to arrange for return of the original documents to us.



August 26, 1997

Mr. Joe Iovino
Supergen, Inc.
2 Annabel Lane, Suite 220
San Ramon, CA 94583

RE: REPORT OF FACILITY DECONTAMINATION SERVICES
SUPERGEN FACILITY, EMERYVILLE, CALIFORNIA

Dear Mr. Iovino:

This report presents the results of facility decontamination activities at a former laboratory facility operated by Supergen, Inc., (Supergen) at 6450 Hollis Street in Emeryville, California (the Site). The decontamination activities were performed by DECON Environmental Services, Inc., (DECON) under contract to Supergen. The materials and methods used to perform the project were based on information provided by Mr. Joe Iovino and Mr. Donald Ebersman of Supergen regarding the history and uses of the Site. The following sections of this report describe background information; a summary of the field activities including packaging and disposal of wastes and usable materials, equipment and ducting removal, decontamination activities, and sample collection and analysis; and additional decontamination and sampling activities.

1.0 BACKGROUND

This section includes descriptions of the Site features, history, and use information provided by Supergen and the decontamination project objectives proposed by DECON and agreed to by Supergen.

1.1: Site Features, History, and Use: According to information provided by Mr. Iovino and Mr. Ebersman, Supergen had leased the former laboratory facility and surrounding office space to support research and development and/or production of Supergen's products, which included bioengineered drugs and cancer chemotherapy agents. Supergen had moved its operations out of the Emeryville facility prior to DECON's involvement in this project. In early May 1997, Mr. Iovino contacted DECON and requested a proposal to perform chemical decontamination of the laboratory facility.

The laboratory room contained a 72-inch fume hood, a reach-in refrigerator/freezer, and a 24-inch counter-top fume hood. Storage cabinets with internal shelves, doors, and a countertop were located along portions of the north, east, and south walls. The 72-inch fume hood was connected by sheet metal exhaust ducting to a blower on the building roof. The reach-in refrigerator/freezer was used to store a variety of chemical products.

At the time of the decontamination activities, the laboratory contained a variety of laboratory equipment, chemical products, and hazardous and non-hazardous wastes. According to Mr. Iovino and Mr. Ebersman, none of the chemical products or wastes in the laboratory were biologically active or infectious (with the exception of a small quantity of bioinfectious waste that was stored in an appropriate container, and which Supergen arranged to have disposed of by a company other than DECON). Supergen provided a tentative inventory of the existing chemicals and wastes at the Site. The inventory indicated that the laboratory contained more than 40 chemical products. Of these, one product (Mitomycin C, or MMC) comprised the majority of the chemical products in the facility. In addition, Supergen provided Material Safety Data Sheets (MSDS) for several of the products considered by Supergen to be of most concern regarding level of toxicity. Of these, Supergen stated that the MMC was by far the most toxic.

23490 Connecticut Street, Hayward, CA 94545-1607 (510) 732-6444 Fax (510) 782-8584 CL#545726

08/26/97 TUE 19:21 [TX/RX NO 8986]

Supergen
August 28, 1997
Page 2

1.2: Decontamination Project Objectives

The objectives of the decontamination activities included the following:

- To properly package and dispose of existing laboratory wastes at the Site.
- To properly package and ship usable chemical products (as defined by Supergen) to another Supergen facility.
- To remove and/or decontaminate existing exhaust ducting, laboratory equipment, and building surfaces including walls, ceilings, floors, and structural members which may have been exposed to hazardous substances.
- To determine the effectiveness of the decontamination activities by collecting wipe samples of surfaces of objects that would remain at the Site and analyzing the samples at an appropriate laboratory for contaminants of concern.

2.0 FIELD ACTIVITIES

The field activities performed at the Site took place between May 30, 1997, and June 16, 1997, and are summarized as follows:

2.1: Package and Coordinate Disposal of Existing Wastes: Existing chemical waste materials in the laboratory room were packaged for shipping in accordance with U.S. Department of Transportation (D.O.T.) regulations. The waste was transported by DECON, a licensed hazardous waste hauler, to the permitted hazardous waste transfer facility operated by Crosby and Overton, Inc., (C&O) at 8430 Amelia Street in Oakland, California. The waste was then transported by C&O, a licensed hazardous waste hauler, to the permitted hazardous waste treatment and disposal facility operated by C&O at 1630 W. 17th Street in Long Beach, California, for recycling and/or disposal by landfilling or thermal treatment, as appropriate. Copies of Hazardous Waste Manifests No. 96554660 and 98554663 are attached to this report.

2.2: Package Usable Materials for Shipping: As directed by Supergen, existing chemicals in the laboratory room were packaged for shipping in accordance with D.O.T. regulations, and shipped via United Parcel Service to the Supergen facility at 3158 Des Plaines Avenue, Suite 14, in Des Plaines, Illinois. A copy of the Straight Bill of Lading for the shipment is attached to this report.

2.3: Removal and Disposal of Fume Hood Exhaust Ducts and Roof-Mounted Blower: The existing fume hood exhaust ducts, blower motor, and roof-mounted equipment were removed from the building. The removed material was decontaminated by vacuuming with a vacuum equipped with a HEPA (High Efficiency Particulate Air) filter and wet wiping with a solution of sodium hypochlorite (chlorine bleach) in water, then transported off the Site for recycling.

2.4: Remove Fume Hoods and Refrigerator/Freezer. The reach-in refrigerator/freezer, counter-top fume hood, and 72" fume hood in the laboratory room were removed from the facility and transported by DECON to the Supergen facility at 1059 Serpentine Lane in Pleasanton, California.

2.5: Decontaminate Laboratory Room: To remove particulates from surfaces, crevices, and accessible spaces, the floors, ceilings, walls, countertops, cabinet interiors, and other remaining objects and surfaces in the laboratory room were vacuumed using a vacuum equipped with HEPA filter. Chemical decontamination and biological sterilization were performed by hand wiping with non-ionic surface wipes and wet wiping with a solution of sodium hypochlorite (chlorine bleach) in water. Waste generated by the performance of the decontamination activities was packaged for shipping in accordance with D.O.T. regulations, then transported and disposed of as described in Section 2.1 above.

2.6: Collection And Analysis Of Confirmation Wipe Samples: Following completion of the decontamination activities, DECON collected confirmation wipe samples from locations throughout the laboratory room on June 2, 1997. The sampling locations were selected to include the areas that were considered to be most likely to have been exposed to the highest levels of possible contamination. For example, the two samples collected from the countertops were collected from locations where equipment layout indicated that chemicals had been most often handled. Sampling locations on the ceiling, walls,

EN:\MY Documents\Coal Estimate at Supergen

Supergen
August 28, 1997
Page 3

and floor were selected to be above, below, or adjacent to the areas where chemicals were most often handled. Wipe samples were collected from a total of fifteen locations. In addition, nine sample blanks were shipped at the request of the analyzing laboratory to facilitate calibration of the analytical method. A diagram illustrating the sampling locations is attached to this report.

The wipe samples were collected using new laboratory filter papers. Prior to collection of a sample, each filter paper was wetted with de-ionized distilled water, then wiped over an area measuring four inches by four inches at the sampling location. The filter paper was then placed immediately into a glass jar which was sealed and labeled with the sampling location, date, and the sampler's initials. The glass jars were immediately placed into a cooler with wet ice and shipped overnight to the analyzing laboratory. The cooler was sealed to prevent light from entering.

The samples were submitted to Custom Testing and Development Laboratory (CTD) in Stanton, Delaware. The samples were analyzed for MMC for the following reasons:

- MMC comprised the majority of the chemical product in the laboratory, and
- MMC was considered to be the most toxic of the chemical products used in the laboratory.

The method used by CTD to analyze the samples is described in CTD's report which is attached to this report. In summary, the analysis by CTD indicated that MMC was not detected at or above laboratory detection limits in 12 of the 15 samples submitted. Low concentrations of MMC were detected in three of the samples (SG-1, SG-2, and SG-4). Samples SG-1 and SG-2 were collected from the laboratory room ceiling, and sample SG-4 was collected from the laboratory room floor. However, according to Mr. Robert S. Lenklewicz of CTD, the source of the MMC in the three samples was likely cross-contamination in the laboratory. Therefore, Supergen requested that DECON collect additional samples from the three locations.

3.0 ADDITIONAL DECONTAMINATION AND SAMPLING ACTIVITIES

On June 18, 1997, DECON returned to the Site and performed additional decontamination and sampling activities. The ceiling and the floor were wet wiped with a solution of sodium hypochlorite (chlorine bleach) in water. Following completion of decontamination activities, confirmation wipe samples were collected from the same locations where samples SG-1, SG-2, and SG-4 had been collected. The three samples (Ceiling 1, Ceiling 2, and Floor 1) were collected, packaged, shipped, and analyzed as described in previous sections of this report. The results of laboratory analysis by CTD indicated that MMC was not detected at or above laboratory detection limits in any of the three samples submitted. The results of confirmation wipe sample laboratory analyses for MMC are included in CTD's report which is attached to this report.

4.0 CLOSURE

This report documents facility decontamination activities performed by DECON at Supergen's Emeryville facility. If you have any questions regarding this report, please call me at (510) 732-6444.

Sincerely,

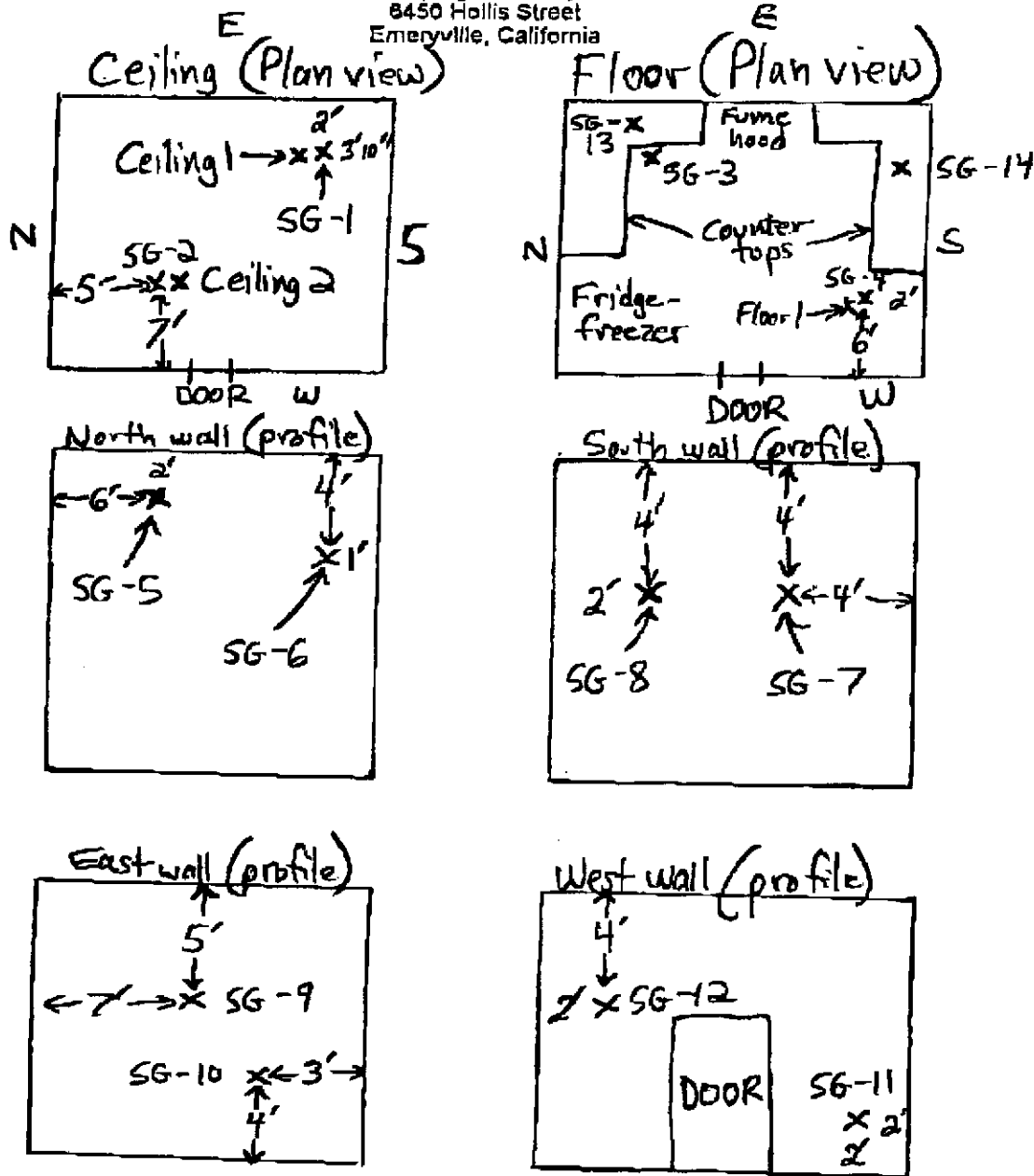


William E. Bassett, Jr.
Project Manager

Supergen
August 26, 1997
Page 4

CONFIRMATION WIPE SAMPLING LOCATIONS

Supergen Facility
8450 Hollis Street
Emeryville, California



Samples collected by DECON Environmental Services on June 2, 1997, and June 16, 1997.

State of California—Environmental Protection Agency
 Form Approved OMB No. 2050-0039 (Expires 9-30-96)
 Please print or type. Do not duplicate for use on other (17-pink) copies.

See Instructions on back of page 6.

Department of Toxic Substances Control
 Sacramento, California

IN CASE OF EMERGENCY OR SPILL, CALL THE NATIONAL RESPONSE CENTER 1-800-474-8801. WITHIN CALIFORNIA, CALL 1-800-837-7330

UNIFORM HAZARDOUS WASTE MANIFEST		1. Generator's US EPA ID No. CA C 0 0 0 7 4 1 4 9 6 2 2 B 2 A	Manifest Document No. 2 2 B 2 A	2. Page 1 of 1	Information in the shaded areas is not required by Federal law.
3. Generator's Name and Mailing Address SUPERGEN, Inc. 2 Annabel Lane, Suite 220 San Ramon, CA 94583		6. US EPA ID Number CA D 9 8 2 5 2 4 4 8 0		98554660	
4. Generator's Phone (510) 327-0200		7. Transporter 1 Company Name DECON Environmental Services, Inc.		(510) 732-3300	
5. Transporter 1 Company Name DECON Environmental Services, Inc.		8. US EPA ID Number CA D 9 8 2 5 2 4 4 8 0		(800) 820-0424	
7. Transporter 2 Company Name Crosby and Overton, Inc. 8430 Amelia St.		10. US EPA ID Number CA D 0 2 8 4 0 9 0 1 9		(916) 422-0101	
9. Designated Facility Name and Site Address Crosby and Overton 1630 W. 17th Street Long Beach CA 90813		11. US DOT Description (including Proper Shipping Name, Hazard Class, and ID Number)		12. Containers	13. Total Quantity
		a. Waste, Toxic Solid, Inorganic, n.o.s. (lab pack) 6.1, UN2011, PGII 3250		0102 D H	0104010 P
		b. Non-RCRA Hazardous Waste, Liquid (lab Pack)		0102 D H	000910 P
		c. Non-RCRA Hazardous Waste, Solids (lab Pack)		0101 D H	0101715 P
		4.			
17. Additional Description for Materials Listed Above CRO PROCELL 17407 DRUM 15 e.g. 2X355M CRO PROCELL 17407 DRUM 15 e.g. 2X355M CRO PROCELL 17407 DRUM 15 e.g. 2X355M		K. Handling Codes for Waste Listed Above 14-07 14-07 14-03			
13. Special Handling Instructions and Additional Information do not OSHA trained handlers should use NIOSH approved safety equipment. 24hr ER# (510) 475-2901 Site: 6450 Hollis Street, Emeryville, CA					
14. GENERATOR'S CERTIFICATION: I hereby declare that the contents of this manifest are fully and accurately described above by proper shipping name and are classified, packed, marked, and labeled, and are in all respects in proper condition for transport by highway according to applicable international and national government regulations. If I am a large quantity generator, I certify that I have a program in place to reduce the volume and toxicity of waste generated to the degree I have determined to be economically practicable and that I have selected the practicable method of treatment, storage, or disposal currently available to me which minimizes the present and future threat to human health and the environment. OR, if I am a small quantity generator, I have made a good faith effort to minimize my waste generation and select the best waste management method that is available to me and that I can afford.					
Printed/Typed Name BRIAN MARSHFIELD		Signature <i>B. Marshfield</i>		Month 05	Day 30
17. Transporter 1 Acknowledgment of Receipt of Materials		Signature <i>Paul Lopez</i>		Month 05	Day 30
Printed/Typed Name RODNEY E. PETTJOHN		Signature <i>R. Pettjohn</i>		Month 06	Day 03
19. Discrepancy Indication Space					
Printed/Typed Name JOE DURAN		Signature <i>J. Duran</i>		Month 06	Day 15

DO NOT WRITE BELOW THIS LINE.

While: TSDC SENDS THIS COPY TO DTC WITHIN 30 DAYS.
 To: P.O. Box 3600, Sacramento, CA 95812

State of California—Environmental Protection Agency
 Form Approved OMB No. 2050-0039 (Expires 9-30-98)
 Please print or type. Form designed for use on 4 1/2" x 11" typewriters.

See Instructions on back page 6.

Department of Toxic Substances Control
 Sacramento, California

IN CASE OF EMERGENCY OR SPILL, CALL THE NATIONAL RESPONSE CENTER 1-800-424-8802. WITHIN CALIFORNIA, CALL 1-800-852-7350

UNIFORM HAZARDOUS WASTE MANIFEST		1. Generator's US EPA ID No.	Manifest Document No.	2. Page 1	Information in the shaded areas is not required by Federal law.
3. Generator's Name and Mailing Address Supergen, Inc. 2 Annabel Lane, Suite 220 San Ramon, CA 94583 4. Generator's Phone (510) 327-0200		C A C 0 0 0 7 4 2 4 9 6	2 2 8 2 A	1	96554663
5. Transporter 1 Company Name DECON Environmental Services, Inc.		6. US EPA ID Number E A D 9 0 2 4 6 8 1 0 3	(510) 532-6400		
7. Transporter 2 Company Name Crosby and Overton, Inc. 8430 Amelia St.		8. US EPA ID Number C A C 0 0 0 7 4 2 4 9 6	1800-021-0700		
9. Designated Facility Name and Site Address Crosby and Overton 1630 W. 17th Street Long Beach CA 90813		10. US EPA ID Number E A D 9 0 2 4 6 8 1 0 3	(510) 432-5700		
11. US DOT Description (including Proper Shipping Name, Hazard Class, and ID Number)		12. Containers No. Type	13. Total Quantity	14. Unit Wt./Vol	15. Waste Name
a. WASTE FLAMMABLE LIQUID, N.O.S. (METHANOL) 3 UN1993 PG-II		0101 DIF	000008	6	ESI 18001
b. WASTE FLAMMABLE LIQUID, N.O.S. (ETHANOL) 3 UN1993 PG-II		0101 DIF	000106	6	ESI 18001
c. WASTE TOXIC LIQUID, INORGANIC, N.O.S. (LAB PACK) 6.1 UN2811 PG-II		0101 DM	000910	G	ESI 18001
12. Additional Descriptions for Materials Listed Above		13. Handling Codes for Wastes Listed Above			
a. Methanol PROBLEM 1407 Drum 4 3 1 XSD		14-01 19-01			
b. Ethanol PROBLEM 1407 Drum 4 3 1 XSD		14-01 19-01			
c. Poison PROBLEM 1407 Drum 4 3 1 XSD		14-01 19-01			
15. Special Handling Instructions and Additional Information: 40hr OSHA trained handlers should use NIOSH approved safety equipment. 24hr ER# (510) 475-2901 Site: 6450 Hollis Street, Emeryville, CA					
16. GENERATOR'S CERTIFICATION: I hereby declare that the contents of this consignment are fully and accurately described above by proper shipping name and are classified, packed, marked, and labeled, and are in all respects in proper condition for transport by highway according to applicable international and national government regulations. If I am a large quantity generator, I certify that I have a program in place to reduce the volume and toxicity of waste generated to the degree I have determined to be economically practicable and that I have selected the practicable method of treatment, storage, or disposal currently available to me which minimizes the present and future threat to human health and the environment. OR, if I am a small quantity generator, I have made a good faith effort to minimize my waste generation and select the best waste management method that is available to me and that I can afford.					
Printed/Typed Name BRIAN MAXFIELD AS AGENT FOR SUPERGEN		Signature <i>Brian Maxfield</i>		Month Day Year 01 5 3 0 9 17	
Printed/Typed Name Richard Lytle		Signature <i>Richard Lytle</i>		Month Day Year 05 13 0 9 17	
Printed/Typed Name RODNEY E. PETTEJOHN		Signature <i>Rodney E. Pettejohn</i>		Month Day Year 06 03 9 17	
19. Discrepancy Indication Space					
Printed/Typed Name Juel Duran		Signature <i>Juel Duran</i>		Month Day Year 06 01 5 9 17	

DO NOT WRITE BELOW THIS LINE.

3-PART STOCK FORM NO. B-3876

STRAIGHT BILL OF LADING— SHORT FORM

ORIGINAL—NOT NEGOTIABLE

Shipper's No. _____

Carrier's Name: DECON ENVIRONMENTAL SERVICES

Carrier's No. *2282

RECEIVED, subject to the classifications and liability filed herein in effect on the date of the issue of this Bill of Lading.

at 450 HOLLIS ST. EMERYVILLE (Dist.) 5130 1997 FROM SUPER GEN, INC.

the property described herein, in equivalent units, terms, or other conditions of carriage of packages (including, packed, consigned, and delivered as shown below, which and compare the usual carriage being undertaken throughout this country or shipping only, unless otherwise specified in the property under the contract) agree to carry to the initial place of delivery or said destination, if no such contract, letter, or highway order or order, or within the territory of the highway authority, in addition to deliver to another carrier on the route to said destination. It is mutually agreed to to each carrier of bill of lading or any other property, and as in each party of any time interested in all or any of said property, that every carrier so performed hereafter shall be subject to all the conditions and prohibitions of law, whether printed or written, herein contained, including the conditions on back hereof, which are hereby agreed to by the shipper and acceptor for himself and his assigns.

Consigned TO DECON ENVIRONMENTAL SERVICE (Mail in street address for purposes of initial delivery)
on Collect on Delivery shipments, the terms "C.O.D." must appear below consignee's name as otherwise provided in Item 430, Sec. 1

Destination SUPERGEN INC. Street 358 DES PLAINES AVE City St. LOUIS
DES PLAINES County _____ State ILL Zip 60018

Route LOCAL/HIGHWAY/UPS Delivery Address * SAME AS DESTINATION

Delivering Carrier DECON TO UPS TO SUPERGEN Car or Vehicle Initials and No. _____

Collect on Delivery \$ N/A And Remit to N/A

Subject to Section 7 of conditions, if this shipment is to be delivered to the consignee's named residence for the consignee, the consignee shall sign the following statement:
 The carrier shall not make delivery of this shipment without payment of freight and all other lawful charges.

Signature of Consignee _____

C. O. D. Charges to be Paid by Shipper Consignee

It always are to be prepaid, with or status here. "To Be Prepaid."

Received by _____ in payment of the charges on the property described herein.

Agent or Cashier _____

The signature hereon is not valid unless signed by the consignee (consignee).

Charges advanced: _____

1. The two conditions used by this shipment conform to the specifications set forth in the two model's conditions shown, and all other requirements of Title 41 of the Uniform Freight Classification and Rule 6 of the National Motor Freight Classification.
 2. Shipper's liability in form of stamp is a part of bill of lading approved by the Interstate Commerce Commission.

No. Packages	N.M.	Kind of Package, Description of Articles, General Marks, and Markings	Weight (Subject to Tare)	Class or Rate	Charge Column
1		5 gl. bucket w/ Etiocholanedione			
1		5 gl. bucket w/ ENCAPSIN HB			
1		5 gl. bucket w/ MISC. PRESCRIPTIONS			
1	X	TOXIC SOLID, Inorganic, N.O.S. (MITOMYCIN) 6.2 UN3208 PG=II			
MSDS ENCLOSED IN BUCKETS					

If the shipment is made by a carrier by water, the law requires that the bill of lading shall state whether it is carrier's or shipper's weight.
 NOTE - Where the rate is dependent on value, shipment are required to state specifically in writing the agreed or declared value of the property.

The agreed or declared value of the property is hereby specifically stated by the shipper to be not exceeding _____

Bob Taylor Shipper, Per SUPERGEN Decon Environmental Agent
 Permanent post-office address of shipper, AGENT FOR Per Bob Taylor

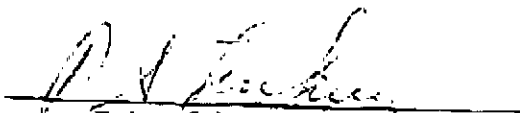
1

Custom Testing and Development
1300 First State Blvd., Suite C
Stanton, DE 19804
(302) 636-0202 phone
(302) 636-0204 fax

10 JULY 1997

REPORT ON
MITOMYCIN RESIDUES
FOLLOWING DECONTAMINATION
OF SUPERGEN FACILITY

Submitted by


Robert S. Lenkiewicz
Director, Product Development
& Analytical Services

c:\ku\mms\1997\analytical\wipes 7-10.rpt

Page 1 of 5

Report on Mitomycin Residues Following Decontamination of SuperGen Facility

SUMMARY

Based on the measured limit of determination for Mitomycin in the wipes, all seventeen-tested 12cm wipe samples (floor) showed less than .2µg Mitomycin. The three 15cm wipe samples (2 ceiling, 1 floor) were found to have less than .3µg Mitomycin.

INTRODUCTION

This report describes the development of the analytical method and its application to test samples of wipes used to detect any residue of Mitomycin (hence referred to as MMC) in a facility occupied by SuperGen. The wipes were applied to various surfaces as described in this report. The wiping process and decontamination were performed by DECON Environmental Services Services Inc. of Hayward, California.

The wipes were extracted with a known volume of deionized water and any extracted Mitomycin was measured by high pressure liquid chromatography (HPLC).

The analytical procedure developed and its limit of determination are described.

EXPERIMENTAL

A. Limit of Determination / Accuracy

An accurate volume of a known concentration of MMC was added to a dry blank wipe which was placed in a screw capped culture tube to which was added a sufficient volume of deionized water for a final volume of 5.0 mL. The extraction was performed by repeatedly inverting the tube by hand for 5 minutes or using a Fisher Roto-Rack for 5 minutes. The supernatant water in each tube was analyzed by HPLC for Mitomycin concentration at the following HPLC conditions:

Column: Diphenyl reverse phase, 5 micron, 4.0mm I.D.,
30cm length at 28-35°C
Mobile Phase: 250mL methanol, HPLC grade
5 mL 0.83N acetic acid
1.54 g. ammonium acetate, HPLC grade
q.s. HPLC grade water to 1000mL
If HPLC grade materials are used, there is no need to filter through
a 0.45µ filter.
Flow Rate: 1.0 +/- 0.1 mL/min.
Injection Volume: 5 microliters
Detector Wavelength: 365nm at 1.0AUFS
Temperature: 30-35°C
Peak Measurement: Peak height

The accuracy of the method as determined by the recovery of known amount of MMC is shown by the data in Table I.

Report on Mitomycin Residues Following Decontamination of SuperGen Facility

TABLE I

**SPIKING OF BLANK (DRY) WIPES
WITH MITOMYCIN AND RECOVERY RATES**

Wipe Diameter	$\mu\text{g MMC}$ Added ⁽¹⁾	Theoretical MMC in Extract $\mu\text{g/mL}$	$\mu\text{g/mL MMC}$ Found in Extract	% Recovered
11cm	15 μg	3.0 $\mu\text{g/mL}$	3.57 $\mu\text{g/mL}$	119
11cm	7.5 μg	1.5 $\mu\text{g/mL}$	1.37 $\mu\text{g/mL}$	91
11cm	1.5 μg	0.3 $\mu\text{g/mL}$	0.3 $\mu\text{g/mL}$	100
12cm	7.5 μg	1.5 $\mu\text{g/mL}$	1.28 $\mu\text{g/mL}$	85

Reference: Lab book, pp. 45-49, 34

(1) The MMC was added using an appropriate volume of a 15 $\mu\text{g/mL}$ MMC aqueous solution.

B. Limit of Determination

The lowest concentration of MMC in the extract which can be reproducibly measured on separate days is used for calculating the limit of determination of MMC on a wipe. The limit differed for some wipes due to the larger volume of water needed to extract a larger size wipe. The lowest concentration was experimentally measured by diluting a known concentration of MMC in water and measuring the signal obtained on the chromatograph. This value was found to be 0.03 $\mu\text{g/mL}$. The chromatographic response obtained using the HPLC conditions described above is shown in Figure 1. To calculate the limit of determination for each wipe, the volume of water used to extract each wipe is multiplied by the lowest concentration measurable.

C. Analysis of Wipes Used to Contact Decontaminated Surfaces

Upon receipt at Custom Testing & Development, the samples were placed in a freezer. The wipes are described as round laboratory filter papers of various sizes. Samples were removed from the freezer and each wipe weighed to determine the amount of water on the wetted test samples. The volume of water was calculated for each wipe by subtracting the weight of a dry wipe of the same size as the wet wipe from the weight of the wet wipe. The difference, in grams, was taken as the volume in mL on each wipe. The wipes were placed in a screw cap culture tube. A sufficient volume of water was added to each test sample to bring the total volume in contact with each wipe as shown in Table II under "Extraction Volume." The tubes were shaken by hand for 5 minutes or placed on a Fisher Roto-Rack for 5 minutes. Each sample was chromatographed within one hour of addition of water used for extraction. Chromatograms of each sample reported in Table II are labelled as Figures 2 through 23.

Report on Mitomycin Residues Following Decontamination of SuperGen Facility

D. Discussion:

The chromatographic conditions and extraction procedure demonstrates the ability of the method to accurately recover Mitomycin from the test wipes as shown in Table I.

The sensitivity of the method, 0.2 μg MMC for 12cm diameter wipes and 0.3 μg MMC for 15cm diameter wipes has been calculated based on the ability to measure the concentration in the extraction volume shown in Figure I. These values are lower than those reported in the summary report dated 19 June 1997. Those values were based on a quick conservative evaluation whereas the values reported in this report can be confirmed by a more rigorous review of the experimental method and data analysis.

The data obtained on all test wipes reported in Table II indicate no detectable levels of MMC on any of the test wipes examined. The limit of determination, also referred to as the sensitivity of the method, is reported as 0.2 μg MMC for 12cm diameter wipes and 0.3 μg MMC for 15cm diameter wipes.

The significance of the levels found and the level of detection as it applies to equipment and facility cleaning in a manufacturing facility is discussed in an articles by K.M. Jenkins and A. J. Vanderwieien entitled "Cleaning Validation: An Overall Perspective," in *Pharmaceutical Technology* p 60-73, (1994).

Report on Mitomycin Residues Following Decontamination of SuperGen Facility

TABLE II

**MITOMYCIN CONTENT OF WIPES USED ON VARIOUS SURFACES
AFTER DECONTAMINATION OF SUPERGEN FACILITY**

Sample #	Wipe diameter	Location	Extraction volume	µg/wipe
Ceiling 1	15cm	Ceiling	9.0mL	<0.3µg
Ceiling 2	15cm	Ceiling	9.0mL	<0.3µg
SG-3	12cm	Floor	6.0mL	<0.2µg
Floor 1	15cm	Floor	9.0mL	<0.3µg
SG-5	12cm	N-Wall	6.0mL	<0.2µg
SG-6	12cm	N-Wall	6.0mL	<0.2µg
SG-7	12cm	S-Wall	6.0mL	<0.2µg
SG-8	12cm	S-Wall	6.0mL	<0.2µg
SG-9	12cm	E-Wall	6.0mL	<0.2µg
SG-10	12cm	E-Wall	6.0mL	<0.2µg
SG-11	12cm	W-Wall	6.0mL	<0.2µg
SG-12	12cm	W-Wall	6.0mL	<0.2µg
SG-13	12cm	Countertop	6.0mL	<0.2µg
SG-14	12cm	Countertop	6.0mL	<0.2µg
SG-15	12cm	Inside L-Cabinet	6.0mL	<0.2µg
SG-16	12cm	Wet Blank	6.0mL	<0.2µg
SG-17	12cm	Wet Blank	6.0mL	<0.2µg
SG-18	12cm	Wet Blank	6.0mL	<0.2µg
SG-19	12cm	Wet Blank	6.0mL	Sample lost
SG-20	12cm	Dry Blank	6.0mL	<0.2µg
SG-21	12cm	Dry Blank	6.0mL	<0.2µg
SG-22	12cm	Dry Blank	6.0mL	not tested
SG-23	12cm	Dry Blank	6.0mL	Used for recovery study



CHAIN OF CUSTODY REPORT

JOB NUMBER AND NAME: 2282 - SUPERGEN INC.				ANALYSIS REQUESTED					
REPORT AND BILL TO: DECON Environmental Services, Inc. 23490 Connecticut Street Hayward, CA 94545 (510) 732-8444				TRIP/ROUND TIME: <div style="border: 1px solid black; height: 20px; width: 100%;"></div>					
SAMPLER: BRIAN MANSFIELD			DATE: 6/2/97						
SAMPLE ID/ LOCATION	SAMPLE DESCRIPTION	CONTAINERS NUMBER	TYPE	SAMPLING TIME/DATE	REMARKS				
S6-1 thru S6-4	walls, ceilings, flows	14	glass	X	DECON will supply diagram				
S6-15	inside cabinet	1	glass	X					
S6-16 thru 19	Blanks w/ H ₂ O	4	glass	X					
S6-20 thru 23	Blanks w/o H ₂ O	4	glass	X					
S6-24	Blank (empty jar)	1	glass	X					
					NOTE: ALL SAMPLES WERE WIPE SAMPLES				
RELINQUISHED BY: <i>B. Mansfield</i>		DATE: 6/2/97	TIME: 1:40 p.m.	RECEIVED BY:					
RELINQUISHED BY:		DATE:	TIME:	RECEIVED BY:					
RELINQUISHED BY:		DATE:	TIME:	RECEIVED IN LAB BY:					
				Laboratory Use Only:					
				Were samples:	<table border="1" style="width: 100%; text-align: center;"> <tr> <th style="width: 50%;">Yes</th> <th style="width: 50%;">No</th> </tr> <tr> <td> </td> <td> </td> </tr> </table>	Yes	No		
Yes	No								
				Preserved/on Ice?	<table border="1" style="width: 100%; text-align: center;"> <tr> <th style="width: 50%;">Yes</th> <th style="width: 50%;">No</th> </tr> <tr> <td> </td> <td> </td> </tr> </table>	Yes	No		
Yes	No								
				In good condition?	<table border="1" style="width: 100%; text-align: center;"> <tr> <th style="width: 50%;">Yes</th> <th style="width: 50%;">No</th> </tr> <tr> <td> </td> <td> </td> </tr> </table>	Yes	No		
Yes	No								
				Labeled?	<table border="1" style="width: 100%; text-align: center;"> <tr> <th style="width: 50%;">Yes</th> <th style="width: 50%;">No</th> </tr> <tr> <td> </td> <td> </td> </tr> </table>	Yes	No		
Yes	No								

* G = Grab C = Composite W = Wipe

08/26/97 TUE 19:21 ITX/RX NO 898A1

08/28/97 THU 14:37 FAX 5103277347 SUPERGEN 510 782 8584 P.14

014

DECON

CHAIN OF CUSTODY REPORT

015 P.15 P.1/1

510 782 8584

08/28/97 THU 14:37 FAX 5103277347 SUPERGEN
AUG-26-97 07:19P DECON Environmental
RUS CO 31 13-30 CUSTOM TESTING DEV 502-655-6204

JOB NUMBER AND NAME: <i>Supergen/Emeryville</i>				ANALYSES REQUESTED				FORWARDED TIME:				
REPORT AND BILL TO: DECON Environmental Services, Inc. 23490 Connecticut Street Hayward, CA 94545 (510) 782-8644				DATE: <i>6/16/97</i>								
SAMPLER: <i>Bill Bassett</i>		DATE: <i>6/16/97</i>		<i>M. to myca</i>								
SAMPLE ID/ LOCATION	SAMPLE DESCRIPTION	CONTAINER NUMBER / VOLS	SAMPLING TIME/DATE					REMARKS				
<i>Ceiling #1</i>	<i>wipe 4"x4"</i>	<i>1</i>	<i>4 PM</i>					<i>X</i>	<i>Wipes wetted with distilled water</i>			
<i>Ceiling #2</i>	<i>" "</i>	<i>1</i>	<i>4 PM</i>					<i>X</i>				
<i>Floor #1</i>	<i>" "</i>	<i>1</i>	<i>4 PM</i>	<i>X</i>								
RELINQUISHED BY: <i>Wm. E. Bassett</i>		DATE: <i>6/16/97</i>	TIME: <i>4:15 PM</i>	RECEIVED BY:		Laboratory use only		Yes	No			
RELINQUISHED BY:		DATE:	TIME:	RECEIVED BY:		preserved on ice						
RELINQUISHED BY:		DATE:	TIME:	RECEIVED IN LAB BY:		in good condition						
						labeled						

* G = Grab C = Composite M = Mipe

08/26/97 TUE 19:21 [TX/RX NO 8986]