Catalytica
Pharmaceuticals

September 21, 2001

Cheryl W. Hannah
Waste Management Analyst
NCDENR, Solid Waste Section
1646 Mail Service Center
Raleigh, NC 27699-1646

Dear Ms. Hannah:

Enclosed is the most recent Waste Minimization Plan for DSM Catalytica Pharmaceuticals in Greenville, NC. (I am also sending a copy to Bobby Nelms in Washington.)

Sincerely,

Mike Folk

Mike Folk
Senior Environmental Engineer

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DSM Catalytica Pharmaceuticals, Inc.

Waste Minimization Plan

September, 2001

Why does DSM Catalytica Pharmaceuticals need a Waste Minimization Plan?

Because DSM Catalytica's Greenville Site is a Large Quantity Generator of hazardous waste, federal law (RCRA Section 3002(b) and RCRA Section 3005(h)) mandates that the company have a Waste Minimization Plan in effect. This plan is to be a written description of current and projected plans to reduce, prevent or minimize the generation of waste and pollutants by source reduction and recycling.

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1.0 Current Status of Waste Minimization at the Greenville Facility

1.1. Waste Generators

The major areas at the Greenville Facility which generate waste are:

Chemical Manufacturing Operations (CMO)	The principal generator of waste at the site. The chemical processes generate flammable solvents and solid byproducts that are destroyed in the ES incinerators, as well as aqueous wastes which are treated in the WWTP.
Pharmaceutical Production Operations (PPO), including Steriles	These operations generate packaging materials that are treated in the Solid Waste Incinerator, and production rejects.
Sterile Production Operations (SPO)	Production rejects are its principal waste. Clean glass bottles are often rejected.
Office areas	Office paper is the principal waste.
Engineering and Maintenance	Construction Debris, asbestos (removal from buildings), Damaged or obsolete equipment, spent fluorescent light tubes, waste oil
Environmental Operations	Sludge from the wastewater treatment plant, ash from the solid waste incinerator
Dyneema High Performance Fibers (New process scheduled to begin production in October of 2001.)	Scrap polyethylene fibers, rolls of siliconized paper.

1.2 Waste Reduction Opportunities in CMO

The greatest opportunities, and the greatest challenges, for waste minimization are found in the Chemical Manufacturing Operation. The four largest-volume products made in CMO are acyclovir, bupropion, valacyclovir, and zidovudine. The chemical processes for each were developed at the Greenville site, and efforts taken during development to minimize waste streams include the following:

> Optimization of reaction chemistry by ensuring completion of reaction, and by reducing excess reactants to the minimum stoichiometry.
>
> Substitution of objectionable solvents (HAPs and TAPs) such as methylene chloride and chloroform, when possible.
>
> Minimizing the volumes of organic solvents and of water, when used during the product isolation which follows reactions.
>
> Maximizing yield (recoveries) of intermediates and products, to reduce their amounts discarded in filtrates and extracts.
>
> Solvent recovery from process streams, for reuse within the process which generated the waste.
>
> Recycle processes were instituted for certain byproducts (e.g.: the trityl alcohol waste generated in zidovudine production is shipped to Courtalds in Scotland, where it is converted back into trityl chloride for use in our zidovudine process.
>
> Spent catalysts are sent to a catalyst refinery for reclamation of the precious metals (palladium and platinum).

Table 1 shows the waste ratios for several of the products made in CMO. These ratios are calculated using the balanced chemical equations for the chemical reactions in each process, and the amounts of materials consumed in each, according to CMO Master Formulas. The table presents a breakdown by each step of the processes. These data are only for the process itself, and does not include cleanups before or after batches are made, or post-campaign cleanups. The table shows a wide variation in waste production between processes, and is useful in determining where opportunities for waste reduction might be found.

Waste ratios will be determined for new processes as they come to CMO.

Table 1: Waste Ratios

Process Step	Kgs of waste per kg of intermediate *(Process Only)*
Acyclovir:	
ACYA	8.5
ACYJ	0.13
ACYC	12.8
ACYD	17.6
Allopurinol:	
ALLA	3.6
ALLB	9.3
ALLC	27.5
Azathioprine	
AZAA	5.2
AZAB	57.7
AZAC	20.9
AZAD	29.3
Bupropion	
BUPA	18.7
BUPB	9.8
Busulfan	
BUSA	17.0
Leucovorin calcium	
LUCB	40.2
LUCC	32.2
LUCD	13.8
Succinylcholine	
SUCA	2.9
SUCC	6.9
SUCD	10.5

Table 1, continued:

Process Step	Kgs of waste per kg of intermediate *(Process Only)*
Trimethoprim	
TRMA	0.06
TRMB	4.25
Valacyclovir	
VACA	10.6
VACB	6.6
VACC	62.2
VACD	8.4
Zidovudine	
ZIDA	15.9
ZIDC	7.9
ZIDD	14.9
ZIDE	17.4
ZIDF	31.0

Waste ratios for some processes that have been run in Greenville since 1998 are presented below:

Table 1, continued:

Process Step	**Kgs of waste per kg of intermediate *(Process Only)***
Trova	
Step 1	58
Step 2	48.8
Step 3	37.6
Nafoxidine	
Step 1	14.8
Step 2	3.53
Step 3	71.3
Step 4	38.3
Step 5	23.8
Pozen MT-500	
Stage 1	24.5
Stage 2	50.2
Stage 3	23.7

Examination of the Greenville processes shows that most of the process waste comes from the isolation/workup steps rather than from the chemical reactions themselves. A significant amount of waste is also generated from the cleanups. When cleaning validation was instituted it resulted in an increase in the volume of waste generated by the cleanups.

The processes run at the Greenville site are mature, and opportunities for waste reduction and minimization have already been instituted for many. The greatest opportunity for waste minimization will be presented as new processes are brought into CMO, PPO, and SPO as the company grows as a contract manufacturer. Each of these processes will be closely examined for opportunities to recycle waste streams within the process, and to minimize the quantities of waste streams.

1.3 Solid Waste Minimization

1.3.1 Current Situation

The GVL Site Recycling Committee established several recycling programs during the early 1990's, and these programs are now well-established on the site. Awareness of the recycling programs continues to be the key to success in reaching our recycling goals. Recycling awareness training was added to the Lab Safety Manual training and to the Supervisors training. GAP-38, "Rules for Solid Waste Recycling at the Greenville Site" was developed to provide guidance to employees on the site. Messages which promote recycling and provide information are routinely posted on the television bulletin board systems on the site.

The following items are currently being recycled by employees sitewide: office paper, cardboard, aluminum soft drink cans, newspapers, telephone books, scrap metal, equipment and furniture sent for salvage, magazines, triple-rinsed metal and plastic drums from CMO, wooden pallets, fluorescent light tubes.

Fifty-five gallon drums are being sent to Moore Drums in Charleston, SC for recycle.

CMO also uses aluminum pallets instead of wood pallets for transporting materials within the Greenville site, and this further reduces the number of pallets which leave the site. PPO has used stainless steel pallets within their areas for many years. (PPO uses stainless steel pallets because they are cleaner than wood pallets, and this helps keep their production areas clean.) In 2001 PPO began using recyclable FRP pallets.

Glass bottles are also being recycled when recyclers are accepting glass. Glass drink bottles from the cafeterias were recycled for several months, until the cafeterias stopped providing drinks packaged in glass. Now the principal source of glass waste are glass bottles and vials rejected from SPO. In 2001, our local recycler (ECVC) stopped accepting pharmaceutical glass for recycle. (The melting point of this glass is apparently lower than that of beverage glass, and this was interfering with the recycle process at the glass recycling plant.) Also in 2001, the national market for recycle glass experienced a downturn and it became difficult to find recyclers.

One company, EnviroSafe Paints (in Raleigh) states that they have an overseas recycler for glass. DSM Catalytica is now in the process of establishing a glass recycling program with this company.

Recycle of the above-mentioned items prevents these items from being sent to the landfill.

Lead acid batteries are recycled by our local fork lift truck servicer (Yale-Daughtry).

Tools were recently purchased which enable calibration gas cylinders to be emptied on-site and sent to a metal recycler. (Previously, they were discarded as hazardous waste.)

Two significant waste streams which are generated in CMO are the triphenyl carbinol from zidovudine synthesis, and the spent palladium catalyst from valacyclovir synthesis. The triphenyl carbinol is sent to Courtalds Chemical Co. in Scotland where it is converted to triphenyl chloride. This triphenyl chloride is shipped to CMO where it is used in the zidovudine process as if it were virgin triphenyl chloride. Without this recycle process the triphenyl carbinol waste stream would have to be destroyed in the Solid Waste Incinerator.

The following quantities of triphenyl carbinol have been recycled in recent years:

Year	Amount of triphenyl carbinol produced in CMO, and sent for recycling (lbs)
1995	~49,000
1996	~58,000
1997	~64,000
1998	~32,000
1999	~34,000
2000	~9,000

The spent palladium catalyst is sent to catalyst manufacturers' refineries (e.g., Degussa, Johnson Matthey, Engelhard) for reclamation of palladium. The following quantities have been recycled in recent years.

Year	Amount of palladium on carbon catalyst sent for recycling (lbs)
1995	~6,400
1996	~11,400
1997	~19,300
1998	~15,000
1999	~12,400
2000	~22,800

Asthma inhalers, which were received as Returned Goods during the time the site was owned by Glaxo Wellcome, were sent to a recycler for reclamation of the fluorocarbon propellant.

EnviroSafe Paints (mentioned above) also has an overseas recycler for printed aluminum foils, and we are in the process of establishing a recycling program with them for this material.

A new scrap metal recycling program was established in mid-2001. The site is now separating certain scrap metals and collecting them for recycle. This program was established with the cooperation of Seaboard Container, using ARVEE & Associates as their scrap metal dealer. We are collecting stainless steel, aluminum, and copper/brass in three separate containers for recycle. Mixed scrap metal is also being collected.

SOP-CORP-270 was established to provide sitewide rules for recycling.

Table 2, Summary of Recycling Efforts

YEAR	RECYCLE (TONS)	NET DESTRUCTION ACHIEVED FOR ON-SITE INCINERATION IN SWI (INCINERATED) (TONS)	LANDFILL (TONS)	TOTAL SOLID WASTE GENERATED (TONS) *(Does not include nonrecyclable leaf, sludge, and ash)*	% RECYCLE (EST.)	% REDUCTION (EST.)
1990						
1991						
1992	604	1,342	1,898	3,844	16%	34%
1993	708	1,831	1,149	3,688	19%	41%
1994	1,133	1,685	610	3,428	33%	45%
1995	1,000	1,466	423	2,877	35%	46%
1996	1,043	1,573	486	3,102	34%	46%
1997	1,018	1,494	412	2,924	35%	46%
1998	1,125	1,314	449	2,626	39%	48%
1999	1,060	1,105	487	2,420	40%	47%
2000	754	1,240	611	2,470	29%	45%

Notes:

Incinerator began full time operations in December 1991

Landfill weights are based on weights recorded at landfill.

Crusher weights are included in the landfill weights.

Total Solid Waste Generated = Recycle + Incinerated + landfill

% Recycle = (Recycle/Total Solid Waste Generated) x 100

% Reduction = (Recycle + Net Destruction on-site)/(Recycle + Net Destruction onsite + Total Solid Waste Generated) x 100

Detailed recycling data are presented in the next six tables.

Table 3
Recycle Data for 1995 (all figures are in pounds)

DATE	Computer Printout	office paper	Cardboard (Grade II)	Cardboard (Grade I)	Wood Pallets	Aluminum Cans	Scrap Metal	Toner Cartridges	News Papers	Plastic Bags	Yard Waste	Salvage	Magazines	TOTAL
Jan-95	3,900	11,900	53,060	20,480	32,388	760	37,210	237	135			5,908		165,978
Feb-95	3,900	11,020	43,400	4,220	34,428	1,000	32,590	57	189		210	11,680		142,694
Mar-95	2,700	11,560	44,200	17,940	32,668	1,460	38,070	147	108	136	1,910	7,820	360	159,079
Apr-95	2,100	9,800	48,840	4,320	31,228	1,060	27,710	75	108	16		17,800	10,500	153,557
May-95	4,200	8,400	69,680	55,960	35,628	1,360	25,370	159	108			46,827	1,060	248,752
Jun-95	2,200	10,860	74,840	23,500	34,668	1,080	23,780	159	27			24,900	700	196,714
Jul-95	2,100	6,480	36,620	0	30,588	1,160	0	0	162			1,170	960	79,240
Aug-95	2,280	6,300	57,500	9,980	31,228	1,120	17,920	81	135			6,740	1,220	134,504
Sep-95	3,160	5,420	40,180	85,960	35,868	860	0	30	162			2,150	960	174,750
Oct-95	3,860	6,820	57,800	31,020	47,068	620	23,790	57	135			38,920	2,001	212,091
Nov-95	5,260	7,000	45,180	8,600	39,788	640	11,590	0	162			28,301	880	147,401
Dec-95	0	1,400	35,720	3,940	35,628	280	8,300	0	135	135		99,554	180	185,272
Total	35,660	96,960	607,020	265,920	421,176	11,400	246,330	1,002	1,566	287	2,120	291,770	18,821	2,000,032

Table 4
Recycle Data for 1996 (all figures are in pounds)

DATE	Computer Printout	office paper	Cardboard(Grade II)	Cardboard (Grade I)	Wood Pallets	Aluminum Cans	Scrap Metal	Phone Books	News-Papers	Glass Bottles	Lead acid Batteries	Salvage	Magazines	TOTAL
Jan-96	2,800	5,600	46,680	7,160	32,228	820	22,420		135	[illegible]		53,705	1,400	172,948
Feb-96	1,060	7,880	42,580	47,000	39,348	700	0		162	[illegible]	3,660	30,725	1,060	174,175
Mar-96	6,660	1,800	47,720	12,560	40,348	1,260	23,100		162	[illegible]		11,500	0	145,110
Apr-96	7,520	2,100	47,280	2,800	35,388	760	41,270		162	[illegible]		14,607	1,060	152,947
May-96	4,060	3,320	64,280	6,960	41,668	560	12,330		196	[illegible]		61,324	520	195,218
Jun-96	0	4,380	67,820	7,700	39,228	1,000	40,070		224	2,060		31,602	0	194,084
Jul-96	0	3,460	44,180	85,820	40,668	580	21,720		224	2,420		10,241	360	209,673
Aug-96	0	7,180	85,940	34,080	49,468	480	21,700		140	47,760		22,506	0	269,254
Sep-96	0	7,360	46,880	12,500	63,108	440	0		280	2,620		21,664	0	154,852
Oct-96	0	12,080	55,480	8,100	43,308	920	19,300	2,800	196	2,960	7,984	5,602	0	158,730
Nov-96	0	8,400	59,740	26,320	53,548	840	1,630		196	2,280	7,400	3,381		163,735
Dec-96	0	4,200	34,640	4,140	47,628	360	0		556	1,700		1,202	1,060	95,486
Total	22,100	67,760	643,220	255,140	525,936	8,720	203,540	2,800	2,633	61,800	19,044	268,059	5,460	2,086,212

Table 5
Recycle Data for 1997 (all figures are in pounds)

DATE	Drums	Office paper	Cardboard (Grade II)	Cardboard (Grade I)	Wood Pallets	Aluminum Cans	Scrap Metal	Light Bulbs (LCM's)	News Papers	Glass Bottles	Lead acid Batteries	Salvage	Magazines	TOTAL
Jan-97	18,000	8,220	58,980	8,480	41,348	180	35,968	0	224	1,500	0	7,109	1,760	181,769
Feb-97	18,000	7,360	48,200	0	66,628	360	16,138	1,259	168	860	0	8,474	1,400	168,847
Mar-97	18,000	9,100	47,520	0	39,268	260	18,905	0	196	340	12,865	5,223	700	152,377
Apr-97	18,000	4,200	56,320	11,540	58,348	800	17,263	0	196	6,240	0	0	360	173,267
May-97	18,000	5,780	56,080	3,200	47,468	640	9,080	0	168	9,600	300	783	520	151,619
Jun-97	18,000	6,480	122,600	17,580	49,588	620	26,941	2,145	196	0	0	1,400	700	246,250
Jul-97	9,000	6,660	59,700	15,480	48,228	720	45,007	0	168	0	3,200	0	180	188,343
Aug-97	18,000	8,360	49,160	15,480	57,428	440	25,880	0	140	80,540	0	0	1,084	256,512
Sep-97	18,000	7,880	45,500	0	33,908	600	10,660	997	154	0	0	0	520	118,219
Oct-97	18,000	7,520	46,700	0	47,028	560	7,920	0	168	0	0	0	700	128,596
Nov-97	18,000	9,460	44,060	0	31,028	320	30,360	0	196	0	0	0	700	134,124
Dec-97	18,000	3,320	40,260	3,760	37,188	380	22,690	801	420	0	8,500	0	360	135,679
Total	207,000	84,340	675,080	75,520	557,456	5,880	266,812	5,202	2,394	99,080	24,865	22,989	8,960	2,035,602

Table 6

Recycle Data for 1998 (all figures are in pounds)

DATE	Drums	Office paper	Cardboard (Grade II)	Cardboard (Grade I)	Wood Pallets	Aluminum Cans	Scrap Metal	Miscellaneous (toner cartridges, phone books)	Light Bulbs (LCM's)	News Papers	Glass Bottles	Lead acid Batteries	Salvage	Magazines	TOTAL
Jan-98	18,000	8,920	60,140	0	36,188	740	8,480	0	0	168	0	0	930	700	134,266
Feb-98	18,000	8,220	50,300	0	42,828	1,300	16,340	38,214	0	196	0	0	0	520	175,918
Mar-98	18,000	11,900	50,580	0	37,468	500	14,730	0	1,500	196	0	0	0	1,220	136,094
Apr-98	18,000	8,920	37,580	0	25,228	440	20,010	0	0	196	0	0	0	880	111,254
May-98	18,000	8,060	44,100	0	40,628	380	25,268	0	0	196	0	11,730	77,500	700	226,562
Jun-98	18,000	4,380	53,220	0	41,108	640	58,870	0	0	168	0	0	48,300	520	225,206
Jul-98	18,000	8,400	55,520	0	31,148	880	30,590	0	0	168	0	0	374	880	145,960
Aug-98	18,000	4,020	170,300	0	34,108	360	30,870	0	1,400	196	0	0	680	520	260,454
Sep-98	18,000	2,460	74,500	0	44,028	700	16,150	1,170		224	0	8,090	6,704	180	172,206
Oct-98	18,000	5,780	58,600	0	51,348	600	45,988	21,143	0	168	0	0	421	540	202,588
Nov-98	18,000	7,180	171,460	0	41,108	500	14,960	0	0	168	22,787	0	7,809	700	284,672
Dec-98	18,000	7,700	45,980	0	39,428	560	45,650	0	0	196	10,360	0	6,000	700	174,574
Total	216,000	85,940	872,280	0	464,616	7,600	327,906	60,527	2,900	2,240	33,147	19,820	148,718	8,060	2,249,754

Table 7
Recycle Data for 1999 (all figures are in pounds)

DATE	Drums	Office paper	Cardboard (Grade II)	Cardboard (Grade I)	Wood Pallets	Aluminum Cans	Scrap Metal	Miscellaneous (toner cartridges, phone books)	Light Bulbs (LCM's)	News Papers	Glass Bottles	Lead acid Batteries	Salvage	Magazines	TOTAL
Jan-99	18,000	7,540	52,820	5,360	44,228	520	20,980		1,590	196	0	0	3,495	880	155,609
Feb-99	18,000	6,660	50,000	0	41,508	580	29,420		0	168	0	8,300	5,302	880	160,818
Mar-99	18,000	9,280	57,240	0	58,428	360	46,680		0	320	2,520	0	10,353	700	203,881
Apr-99	18,000	7,360	59,560	0	35,588	600	30,950		0	196	0	0	1,300	880	154,434
May-99	18,000	7,700	52,920	0	46,868	580	30,260		2,111	168	0	0	0	360	158,967
Jun-99	18,000	8,900	65,720	0	44,468	640	16,400		0	120	0	8,090	0	1,100	163,438
Jul-99	18,000	5,260	63,340	6,980	27,508	460	175,540		0	168	0	0	0	540	297,796
Aug-99	18,000	3,500	65,980	48,820	42,788	640	71,230		1,300	100	5,600	0	0	180	258,138
Sep-99	18,000	3,160	25,620	0	24,508	400	15,320		0	60	0	0	0	0	87,068
Oct-99	18,000	7,000	62,800	18,940	21,788	640	17,150	3,885	0	200	0	8,730	0	880	160,013
Nov-99	18,000	7,160	62,800	18,940	29,628	640	18,000		0	200	0	0	0	880	156,248
Dec-99	18,000	4,900	47,200	0	76,628	640	16,260		0	16	0	0	0	540	164,184
Total	216,000	78,420	666,000	99,040	493,936	6,700	488,190	3,885	5,001	1,912	8,120	25,120	20,450	7,820	2,120,594

Table 8
Recycle Data for 2000 (all figures are in pounds)

DATE	Drums	Office paper	Cardboard (Grade II)	Cardboard (Grade I)	Wood Pallets	Aluminum Cans	Scrap Metal	Miscellaneous (toner cartridges, phone books)	Light Bulbs (LCM's)	News Papers	Glass Bottles	Lead acid Batteries	Salvage	Magazines	TOTAL
Jan-00	18,000	9,800	46,820	6,734	24,108	560	9,000			176	2,680		0	360	118,238
Feb-00	21,420	928	43,060	0	43,468	400	29,500		2,972	240	0	100	0	880	142,968
Mar-00	18,000	6,300	99,720	4,090	35,388	624				196			0	1,240	165,558
Apr-00	23,215	5,600	44,760	14,500	30,188	360	35,000						0	540	154,163
May-00	18,000	5,600	52,760	0	31,388	120	33,000						0	880	141,748
Jun-00	18,000	5,080	58,120	0	0	504		14,326			0	0	0	540	96,570
Jul-00	18,000	4,740	32,840	9,346		336	12,000			200			0	360	77,822
Aug-00	18,000	5,420	47,880		7,200	480	11,000			186			4,568	700	95,434
Sep-00	18,000	6,660	39,240		18,200	0	15,000						3,042	880	101,022
Oct-00	18,000	7,700	58,120	8,440	33,960	360	15,000			56			0	1,240	142,876
Nov-00	18,000	6,660	58,840		47,440	396		2,626		56			0	0	134,018
Dec-00	18,000	3,680	47,400		15,400	270							35,000	540	120,290
Total	224,635	68,168	629,560	43,110	286,740	4,410	159,500	16,952	2,972	1,110	2,680	100	42,610	8,160	1,490,707

In 1995 the committee agreed to define recyclable waste as that which the company could feasibly recycle. This definition therefore excludes digitalis leaf, wastewater treatment sludge and incinerator ash. The recycling rate is now based on a comparison of total waste generated, excluding the above three waste streams, to the amount recycled. From 1995 through mid-1997, the rate of recycle was approximately 35 percent and the rate of reduction was about 46 percent.

The Greenville Site's goal is the same as the State's goal, namely, to reduce the municipal solid waste stream by 40% by June 30, 2001. The data presented in Table 2 indicates the company is in fact exceeding this goal.

EPA's "Lighting Waste Disposal - Lighting Upgrade Manual" published in 1994 states that the small quantities of mercury found in fluorescent lamps can be potentially harmful to the environment and human health. Thus, lamps containing mercury may be classified as hazardous waste. A recycling program was established to prevent these lamps from being discarded to the landfill. SOP-CORP-55 (Recycling of Lights Containing Mercury) was established to provide sitewide instructions for recycling of these light tubes. All of the departments on-site which replace light tubes are now repackaging the spent bulbs and delivering them to the Environmental Complex. Environment Safety has contracted with Global Recycling Technologies in Massachusetts for recycling of these light tubes.

Recycle Data for Fluorescent Lamps:

YEAR	Pounds of fluorescent tubes recycled
1997	5,075
1998	2,275
1999	5,002
2000	5,885

Costs associated with recycling:

- C*P does not receive any money (nor is C*P charged any money) for any of the items recycled by ECVC. The Seaboard Container Service hauls the recycled cardboard to ECVC, and Catalytica pays $38.82 per haul, and $195 per month for the box rental
- C*P expects to receive money for the scrap metal that is sent to a recycler.
- C*P sometimes receives payment for the items sent to Salvage (when items are sold), but C*P does not receive money for a majority of the items disposed of by Salvage.
- Drums: Recycle of drums is a net cost to the company.
- Fluorescent light tubes: C*P must pay Global about $1.22 per pound for recycling.
- Lead acid batteries: Batteries are removed by Yale-Daughtry at no cost to the company.
- Wood pallets: Bryant's Pallets gives the company $1.00 each for serviceable pallets.
- Aluminum foil labels: EnviroSafe paints has indicated that they intend to charge us fees for transportation which will closely match the costs we currently pay for landfill tipping fees and transportation to the landfill.
- Glass from pharmaceutical operations: . EnviroSafe paints has indicated that they intend to charge us fees for transportation which will closely match the costs we currently pay for landfill tipping fees and transportation to the landfill.

1.4 Hazardous Waste Minimization

1.4.1 Current Situation

The Waste Minimization and Disposal Policy adopted in 1990 when the company was owned by Burroughs Wellcome continues in effect. The current thrust of anticipated environmental laws and regulations requires Catalytica to continue its aggressive programs to implement hazardous waste minimization.

The toluene recovery system was installed in 1994 for the purpose of recovering toluene from ACYA and ACYC, for reuse in either of these steps. This recovered toluene has been recycled as follows:

Year	Amount of Toluene recycled in ACYA and ACYC, lbs
1995	2,469,158
1996	1,829,835
1997	814,038
1998	913,049
1999	1,431,303
2000	2,185,627

Other solvents which have been recovered and reused during this same time frame are (all figures are in pounds):

Year	Chloroform from Azathioprine	Chloroform from Digoxin	SD3A from BUPB	Ethyl acetate from ZIDD	Methylene Chloride from DIGC	Pyridine from MERA	Pyridine from Zidovudine	Toluene from ZIDF	Acetic Anhydride from ACYA
1995	115,615	42,718	35,304	0	304,315	11,590	322,940	134,817	1,285,133
1996	81,360	36,794	55,528	1,599,029	277,820	2,207	556,895	222,957	1,120,708
1997	64,776	47,671	328,269	2,879,854	287,180	1,512	758,186	304,684	293,800
1998	0	65,192	438,367	1,938,735	205,128	490	672,682	154,858	
1999	0	47,161	374,248	1,542,526	301,993	706	574,347	63,903	563,829
2000	0	34,633	685,385	873,579	227,251	525	383,614	30,440	899,574

The total value of these recovered solvents, based on 1997 prices, is as follows:

	1995	1996	1997	Total:
Acetic Anhydride	$511,139	$445,742	$116,854	$1,073,735
Chloroform	$88,753	$66,231	$63,032	$218,015
Ethyl Acetate	$0	$754,191	$1,358,298	$2,112,489
Methylene Chloride	$183,555	$167,574	$173,220	$524,349
Pyridine	$987,205	$1,649,921	$2,241,884	$4,879,011
SD3A	$11,272	$17,729	4104,808	$133,808
Toluene	$436,948	$344,459	$187,722	$969,130
			Total for above:	**$9,910,536**

Decreased production of Trimethoprim at the Greenville site will free up the DMSO recovery facility for use in other processes. (Current plans are to utilize the DMSO recovery system for recovery of tetrahydrofuran from a new process.)

Methylene choride is used in the digoxin process, and is recovered from air emissions via carbon adsorption units. The recovered methylene chloride is recycled within the process. The table below summarizes recent recovery and recycle of this methylene chloride:

(All figures are in pounds.)

	1994	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**
Methylene chloride released from the digoxin process (defined as methylene chloride used, since it replenishes the amount released)	52,430	66,872	88,013	52,724	56,767	57,026	85,450
Methylene chloride recycled in the digoxin process (the amount reported as recovered via the carbon adsorption units):	371,952	304,315	277,820	287,179	205,128	301,993	227,251
Total used (released plus recycled)	424,382	371,187	365,833	339,903	261,895	359,019	312,701
Percent recycle (recycle/total):	**87.6%**	**82.0%**	**75.9%**	**84.5%**	**78.3%**	**84.1%**	**72.7%**

Target: CMO expected to achieve an 84.7% recycle rate for 1998 and the years which follow. They did not meet this target

Chloroform is also recovered and reused in the digoxin process, and the table below summarizes recent recovery and reuse activity.

(All figures are in pounds.)

	1995	1996	1997	1998	1999	2000
Virgin chloroform used in the digoxin process	14,294	16,370	15,969	15,977	19,270	27,864
Chloroform **recovered** from carbon adsorption units and recycled	42,718	36,794	47,672	65,192	47,160	34,633
Total used (virgin plus recycled)	57,012	53,164	63,641	81,168	66,430	62,498
Percent recycle (recycle/total)	**74.9%**	**69.2%**	**74.9%**	**80.3%**	**71.0%**	**55.4%**

Target: CMO expected to achieve a 74.9% recycle rate for 1998 and the years which follow. They did not meet this target.

Chloroform used in Azathioprine B step is also recovered for reuse, with the table below providing a summary:

(All figures are in pounds.)

	1995	1996	1997
Virgin chloroform used in AZAB	53,456	136,695	118,367
Chloroform recovered and **recycled**	115,615	81,360	64,776
Total used (virgin plus recycled)	169,071	218,055	183,143
Percent recycle (recycle/total)	**68.4%**	**37.3%**	**35.4%**

No recycling was done after 1997. This process is no longer run by Catalytica.

The tables below give an historical perspective of the amounts of hazardous waste shipped off-site and the amounts handled on-site.

	1986	1987	1988	1989	1990
Quantity Generated On-Site, lbs.	4,683,914	7,943,544	9,262,336	6,660,937	5,907,473
Quantity Shipped Offsite, lbs (To Commercial TSDF)	1,637,363	2,863,617	1,412,540	43,869	101,668
Quantity Received From Off-Site (RTP)	0	0	0	46,619	97,706
Quantity Treated On-Site, lbs	2,855,971	4,784,733	7,792,638	6,524,895	5,826,319
% Treated On-Site	63.6%	62.6%	84.7%	99.3%	98.3%

	1991	1992	1993	1994	1995
Quantity Generated On-Site, lbs.	5,100,035	8,967,815	8,084,156	9,314,410	13,307,524
Quantity Shipped Offsite, lbs (To Commercial TSDF)	56,155	113,810	80,136	74,126	323,479
Quantity Received From Off-Site (RTP)	128,512	161,163	175,242	178,731	121,983
Quantity Treated On-Site, lbs	5,071,522	9,007,357	8,215,532	9,325,274	12,983,731
% Treated On-Site	98.9%	98.8%	99.0%	99.2%	97.6%

	1996	1997	1998	1999	2000
Quantity Generated On-Site, lbs.	14,879,561	16,038,867	16,148,159	15,871,357	17,385,118
Quantity Shipped Offsite, lbs (To Commercial TSDF)	196,818	118,508	62,392	314,856	192,839
Quantity Received From Off-Site (RTP)	231,519	88,071	0	0	0
Quantity Treated On-Site, lbs	14,682,743	15,920,359	16,085,767	15,556,501	17,192,279
% Treated On-Site	98.7%	99.3%	99.6%	98.0%	98.9%

Catalytica Pharmaceuticals expects to install new processes at the Greenville site under contract to other pharmaceutical companies. In one of the first processes CMO believes that the heptane and toluene waste generated by this process may be recovered for reuse in the existing toluene recovery facility.

New processes coming to the Greenville site will be examined for the possibility of recovering materials from waste streams for their reuse.

2.0 Waste Minimization Plan

Catalytica is pursuing contract manufacturing business from other pharmaceutical companies, and opportunities for waste minimization will be found in these new processes. Environment Safety and CMO will be examining the Process Transfer documents which describe potential new processes and will be exploring opportunities for waste reduction.

2.1 Basics of Waste Minimization

Waste Minimization consists of:

Source Reduction

Material Substitution:	This is a change in one or more of the raw materials used in production in order to reduce the volume or toxicity of waste generated.
Process Modification:	This is the change of existing processes for the purpose of reducing waste at the source.
Good Operating Practices:	Plant Management: Incentives, training, closer supervision, production scheduling
	Materials Handling: Materials tracking and inventory control, spill prevention, material handling and storage procedures, preventive maintenance
	Waste Management: Waste/Environmental Audits, waste stream segregation, waste handling and storage procedures.

Recycling

Recovery and Recycling:	This includes direct reuse of waste material, recovering used materials for a separate use, and removing impurities from waste to obtain relatively pure substances.
Solvent Waste Recycling:	Solvents are used for equipment cleaning, reaction media, extraction media, and coating media.

Steps to Improve Solvent Waste Recovery:

Segregate solvent waste as follows:

- chlorinated from non-chlorinated solvent wastes
- aliphatic from aromatic solvent wastes
- chlorofluorocarbons from methylene chloride
- water wastes from flammables
- Minimize solids concentration in solvent wastes.

Standard costs for waste treatment calculated for 1998 are:

SWI:	\$0.242 per lb
RCRA Incinerators:	\$0.093 per lb
Organic waste	\$18.983 per 1000 gal
Utility Waste	\$4.549 per 1000 gal
Sanitary waste	\$2.401 per 1000 gal

2.2.1 Guidance from EPA

Below is EPA's draft list of chemicals rated according to their aggregate human and ecological risk. A chemical's overall score may range from 18 to 6, with 18 being the highest risk. The EPA states that the list is intended merely to be a guide for prioritizing waste minimization efforts that would principally be voluntary in nature.

The list below is the "full list" of items that are currently being used or have been used in the past at the GVL site.

Name	Rank
Mercury	18
Polychlorinated biphenyls	18
Toxaphene	18
Chlordane	17
Chrysene	16
Barium	14
Nickel	14
Chlorambucil	13
Carbon tetrachloride	13
copper	13
Digoxin	13
Parathion	13
Zinc	13
2- and 3- t-Butyl-4- hyroxyanisole	12
Benzene	12
1,1,1-trichloroethane	11
1,2 - Dichloroethane	11
Chloroform	11
Ethylene oxide	11
Ethylenediaminetetraacetic acid, tetrasodium salt (EDTA)	11
Fluorouracil	11
Hexane	11
Mercuric acetate	11
naphthalene	11
Acrolein	10
Aniline	10
Ethylbenzene	10
Melphalan	10
Methanesulfonyl chloride	10
Morpholine	10
Oleic acid	10
Phosgene	10
Phosphorus oxychloride	10
Picric acid	10
Sodium lauryl sulfate	10
tert-butylamine	10
Trichloroethylene	10
Triethylamine	10
Acrylonitrile	9
Benzenesulfonyl chloride	9
Cyanide	9
Diethylene glycol methyl ether	9

Formaldehyde	9
Heptane, n-	9
Phenacetin	9
Phenol	9
Propionitrile	9
Pyridine	9
Sodium carbonate	9
Sodium cyanide	9
Toluene	9
Xylenes (*m*- , *o*-, and *p*-)	9
4-chlorophenol	8
Benzaldehyde	8
Dioxolane (1,3-dioxolane)	8
Ethyl alcohol	8
Ethyl ether	8
Ethylamine	8
Furans	8
Methyl isopropyl ketone	8
Methyl t-butyl ether	8
Methylamine	8
Methylene chloride	8
Octyl alcohol, n-	8
p-toluenesulfonic acid	8
paraldehyde	8
sec-butylamine	8
Tetrahydrofuran	8
Triethylene glycol monoethyl ether	8
Trimethylamine	8
urea	8
Xylenes	8
Acetaldehyde	7
Acetic acid	7
Acetic acid anhydride (acetic anhydride)	7
Acetone	7
Acetonitrile	7
Amyl acetate	7
Benzyl alcohol	7
Butyl acetate, n-	7
Butyl alcohol, n-	7
Carbon disulfide	7
Chlorobenzoic acid, p-	7
Cyclohexane	7
Ethanol amine	7
Ethylene glycol monomethyl ether	7
Formic acid	7
hydrochloric acid	7
Isopropyl alcohol	7
Oxalic acid	7
Pentane	7
Sodium bicarbonate	7
Valeric acid	7
Butanoic acid	6
Citric acid	6
Ethyl acetate	6
Ethylene glycol	6
Isobutyl alcohol	6

Maleic acid	6
Methanol	6
Methyl ethyl ketone	6
n-propyl alcohol	6
Polyethylene glycol	6
potassium chloride	6
Propionic acid	6
Salicylic acid	6
Sodium Chloride	6
Succinic acid	6

The list below contains only those items which are currently in regular use in significant quantities at the Greenville Site. This list (and the above list) provides guidance when it comes to choosing solvents and reagents, and guidance for prioritizing waste minimization efforts.

Name	Rank
Chlorambucil	13
Carbon tetrachloride	13
Digoxin	13
1,2 - Dichloroethane	11
Chloroform	11
Ethylene oxide	11
Ethylenediaminetetraacetic acid, tetrasodium salt (EDTA)	11
Hexane	11
naphthalene	11
Aniline	10
Melphalan	10
Methanesulfonyl chloride	10
Morpholine	10
Phosphorus oxychloride	10
tert-butylamine	10
Triethylamine	10
Acrylonitrile	9
Benzenesulfonyl chloride	9
Pyridine	9
Sodium carbonate	9
Toluene	9
Xylenes (*m*- , *o*-, and *p*-)	9
Dioxolane (1,3-dioxolane)	8
Ethyl alcohol	8
Methyl isopropyl ketone	8
Methyl t-butyl ether	8
Methylamine	8
Methylene chloride	8
p-toluenesulfonic acid	8
Tetrahydrofuran	8
Acetaldehyde	7
Acetic acid	7
Acetic acid anhydride (acetic anhydride)	7
Acetone	7
Acetonitrile	7
Cyclohexane	7
Formic acid	7
hydrochloric acid	7
Isopropyl alcohol	7
Sodium bicarbonate	7
Citric acid	6
Ethyl acetate	6
Ethylene glycol	6
Methanol	6
Methyl ethyl ketone	6
Polyethylene glycol	6
Sodium Chloride	6

2.2.2 Other Guidance

The principles below are available for further guidance.

The 12 Principles of Green Chemistry

1. Minimize waste generation
2. Maximize atom economy (Synthetic methods should be designed to maximize the incorporation of all materials used in the process into the final product. How many of the reactant atoms end up in the final desired product and how many are wasted?)
3. Minimize the use of toxic ingredients
4. Maximize the product efficacy/toxicity ratio
5. Minimize the use of solvents and other auxiliary substances
6. Maximize the use of renewable resources
7. Minimize energy use
8. Avoid derivitization (use of blocking groups, protection/deprotection, temporary modification of physical/chemical processes) to the lowest practical limit, since such steps can require additional reagents and generate waste.
9. Use catalytic, rather than stoichiometric, reagents
10. Make products that do not persist in the environment
11. Measure and control processes for the prevention of hazardous-substance production
12. Select raw materials and intermediates so as to minimize accidents and exposure.

(from Green Chemistry: Theory and Practice by Paul T. Anastas and Tracy C. Williamson, Oxford University Press.)

Chemistry
The Twelve Principles of Green Chemistry[1]

1. It is better to prevent waste than to treat or clean up waste after it is formed.
2. Synthetic methods should be designed to maximize the incorporation of all materials used in the process into the final product.
3. Wherever practicable, synthetic methodologies should be designed to use and generate substances that possess little or no toxicity to human health and the environment.
4. Chemical products should be designed to preserve efficacy of function while reducing toxicity.
5. The use of auxiliary substances (e.g. solvents, separation agents, etc.) should be made unnecessary whenever possible and, innocuous when used.
6. Energy requirements should recognized for their environmental and economic impacts and should be minimized. Synthetic methods should be conducted at ambient temperature and pressure.
7. A raw material feedstock should be renewable rather than depleting whenever technically and economically practical.
8. Unnecessary derivatization (blocking group, protection/deprotection, temporary modification of physical/chemical processes) should be avoided whenever possible.
9. Catalytic reagents (as selective as possible) are superior to stoichiometric reagents.

10. Chemical products should be designed so that at the end of their function they do not persist in the environment and break down into innocuous degradation products.
11. Analytical methodologies need to be further developed to allow for real-time in-process monitoring and control prior to the formation of hazardous substances.
12. Substances and the form of a substance used in a chemical process should chosen so as to minimize the potential for chemical accidents, including releases, explosions, and fires.

[1] Anastas, Paul T., and Warner, John C. *Green Chemistry Theory and Practice*, Oxford University Press, New York, 1998

2.3 Update on the Waste Reduction Projects planned in 1998:

2.3.1 PROJECT: <u>RECYCLE OF ALUMINUM FOIL LABELS</u>

TARGET AREAS:

Secondary Production (Packaging areas) generate aluminum foil labels on cylindrical rolls, as waste, typically as rejects. ES cannot burn them in SWI because the aluminum melts and flows out of the air draft tubes. They have been sent to the landfill in the past.

U. S. Granules has successfully recovered the aluminum from three pallets of foil sent to them by ES. However, a less expensive option for recycle of aluminum foil labels is now (year 2001) being pursued with EnviroSafe Paints in Raleigh, NC.

WASTE REDUCTION EXPECTED:

This recycling effort could reduce the amount sent to the landfill by about 39,000 lbs per year (estimate).

2.3.2 PROJECT: REDUCE THE AMOUNT OF WATER ADDED DURING NEUTRALIZATION OF ACETONE WASTE IN BUPROPION A STEP

BUPA produces a waste stream no 2164, which is titled "BUPA -Neutralized Acetone Waste". It consists of 390 gallons (from a 500 gal batch) which is 76% water and about 20% acetone (BUPA related substances make up the balance). The WDP specifies that it be sent to AFW. It has a heat of combustion of 1494 BTU/lb.

This waste is produced by adding 250 gallons of water to the aqueous layer from the extraction of the combined toluene phase and toluene washes, and then neutralizing this mixture to pH 4.5 - 6.5 with 20% sodium hydroxide. (ES recently instructed CMO to neutralize all the way to pH 6.5).

TARGET AREAS:

If CMO stops adding the 250 gallons of water to this mixture it could reduce the amount of liquid sent to AFW. Total elimination of the 250 gallons is not likely, since some water is needed to accomplish the neutralization. CMO is now adding 50 gallons instead of 250.

WASTE REDUCTION EXPECTED:

A total of 246 batches of BUPA would be required for production of 74 metric tons of Bupropion. This waste stream could be reduced from 390 gallons per batch to 190 gallons per batch. For 246 batches this gives total reduction from 95,940 gal to 46,740 gallons. The model predicts that ES would reduce our total AFW and SFW (combined from all CMO processes) by 10%.

This is also the equivalent of nearly five tank loads for a 10,000 gallon tank.

The current WDP gives the following composition:

	%, wt	kg
water	76.1%	1123.6
acetone	19.6%	289.4
3-chlorobenzoic acid	3.4%	50.2
3-chlorobenzenemethanol	0.3%	4.4
3-chloropropiophenone	0.2%	3.0
BUPA	0.1%	1.5
t-butylamine	ND	
toluene	ND	

reported volume	390 gal
calculated weight, sg = 1.0	1,477 kg

The concentration of acetone is too high to allow it to go to WWTP.
CMO must send it to AFW.

Proposed modification:

Remove 200 gal of water
This is 757.2 kg

Composition would become:

	%, wt	kg
water	51.3%	366.4
acetone	40.5%	289.4
3-chlorobenzoic acid	7.0%	50.2
3-chlorobenzenemethanol	0.6%	4.4
3-chloropropiophenone	0.4%	3.0
BUPA	0.2%	1.5
t-butylamine		
toluene		
	total:	714.9

This waste would go from 76% water to 51% water, and would still need to be sent to AFW. However, the reduced water content should give it a higher heat content and reduce the burden on the incinerator.

If CMO further reduced the water by adding only 25 gallons, the waste composition becomes:

	%, wt	kg
water	21.4%	94.7
acetone	65.3%	289.4
3-chlorobenzoic acid	11.3%	50.2
3-chlorobenzenemethanol	1.0%	4.4
3-chloropropiophenone	0.7%	3.0
BUPA	0.3%	1.5
t-butylamine		
toluene		
	total:	443.1

ES believes this waste could go to RFW, which would be very advantageous.

If CMO is successful in reducing the amount of water added to this waste, ES will request that the analysis of the waste stream be updated. In particular, the CMO laboratory will be asked to provide: :

Heat of Combustion
Organic chloride
Ash
pH
and also for the water and acetone content.

CAPITAL AND EXPENSE FUNDS REQUIRED TO COMPLETE THE PROJECT:

No capital or expense funds will be required.

ESTIMATED COST SAVINGS:

The cost savings is $37,250 for 1998,(at an estimated cost of $0.20 per kg for incineration costs).

TIME ELEMENT INVOLVED:

Status: in late 1997 CMO lab instructed the BUPA supervisors to reduce the water addition to 50 gallons. This change has been implemented.

The CMO regulatory advisor has determined that Glaxo Wellcome approval is not required to modify waste streams (the GW supply agreement stated that any changes in the process needed their approval).

The change in the Master Formula has no impact on the FDA regulatory filing (it does nothing to the process chemistry).

2.3.4 PROJECT: <u>RECYCLE OF DCU WASTE</u>

TARGET AREAS:

CMO, valacyclovir (Purchasing)

On 9/23/97, the Purchasing Department said that there is renewed interest in this process. It looks like Glaxo wants to go back to Tanabe as the supplier for DCC. (Schweizerhall is the U.S. agent for Tanabe, and Purchasing would like to deal directly with Tanabe.) The price of DCC fluctuates with the Yen, so sometimes CMO saves $4 per kg and sometimes CMO has paid $2 per kg extra for the DCC. Tanabe was developing a process for recycle, and Dartford is interested in it.

WASTE REDUCTION EXPECTED:

The current forecast calls for production of 30,000 kg of valacylovir each year for 1998, 1999, and 2000. This will generate approximately <u>50,547 kg each year of wet cakes of DCU waste</u> (29,385 kg dry basis). Recycle of this material (by conversion into DCC for reuse) could remove this entire amount of waste from the SWI.

CAPITAL AND EXPENSE FUNDS REQUIRED TO COMPLETE THE PROJECT:

Purchasing will need to determine the financial advantage of purchasing the DCC which is produced from the DCU waste. One of the biggest factors will be the shipping costs to send the waste to Japan for reprocessing.

ESTIMATED COST SAVINGS:

It will cost $18,836 annually to destroy this material in the Solid Waste Incinerator, based on current operating costs. Incineration of DCU is known to cause added corrosion to the underfire air draft tubes and to the refractory lining of the solid waste incinerator. ES estimates the annual cost of refractory, tube, and hearth repair attributable to DCU incineration to be $12,500. Thus, about $30,000 per year could be saved in the solid Waste Incinerator operation if DCU was removed from its feedstock.

TIME ELEMENT INVOLVED:

Tanabe currently awaits a decision from Catalytica to pursue this recycle. Tanabe is currently converting their method of manufacture for DCC, and their new process will convert DCU to DCC. They will be buying DCU as the starting material for the process. Glaxo Wellcome in the UK has analyzed DCC that was made from DCU, and found it analytically acceptable. Environment Safety received 300 grams of this DCC from Tanabe's distributor (Schweizerhall) and provided this to the CMO Support Lab for a use-test. Concurrently, the QO Compliance Group has been requested to pursue approval of Tanabe as a supplier. CMO plans to run three lab scale batches using this DCC, and the results will be sent to Glaxo Wellcome for approval of the DCC use.

Update: CMO expected to be able to implement this project by the end of 1998. However, Glaxo Wellcome did not implement this project.

2.3.5 PROJECT: <u>DESTROY THE SPENT DIGOXIN LEAF IN SWI INSTEAD OF SENDING IT TO THE LANDFILL</u>

TARGET AREAS:

Digoxin process:. A small quantity of spent leaf was sent to SWI for destruction. This material burned very well, especially when burned along with DCU. This opens the possibility of it being destroyed on-site in the Solid Waste Incinerator instead of being sent it to the landfill.

It would require that the leaf be drummed, instead of being dropped into a dumpster.

WASTE REDUCTION EXPECTED:

In 1996 CMO sent 790 tons of leaf to the landfill, and during the first 6 months of 1997 CMO sent 543 tons to the landfill.

CAPITAL AND EXPENSE FUNDS REQUIRED TO COMPLETE THE PROJECT:

Implementation would require labor to transfer the leaf into drums. It would also place a greater burden on the CMO material handlers, who would have to transport these drums to SWI.

ESTIMATED COST SAVINGS:

Below are the disposal costs for the spent leaf during 1996 and 1997:

Month	leaf (tons)	No of hauls	Hauling costs	tipping fees	Total Costs
Jan-96	82	13	$758	$2,461	$3,219
Feb-96	77	11	$641	$2,322	$2,963
Mar-96	75	13	$758	$2,245	$3,003
Apr-96	84	11	$641	$2,520	$3,161
May-96	59	9	$525	$1,776	$2,301
Jun-96	26	7	$408	$920	$1,328
Jul-96	52	9	$525	$1,859	$2,384
Aug-96	81	14	$816	$2,926	$3,742
Sep-96	79	10	$583	$2,834	$3,417
Oct-96	72	13	$758	$2,598	$3,356
Nov-96	75	14	$816	$2,695	$3,511
Dec-96	29	4	$233	$1,040	$1,273
Total	790	128	$7,462	$26,196	$33,658

Month	leaf (tons)	No of hauls	Hauling costs	tipping fees	Total Costs
Jan-97	68	14	$847	$2,658	$3,505
Feb-97	59	12	$726	$2,126	$2,852
Mar-97	65	12	$726	$2,323	$3,049
Apr-97	57	12	$726	$2,040	$2,766
May-97	65	12	$726	$2,328	$3,054
Jun-97	47	10	$605	$1,701	$2,306
Jul-97	45	7	$428	$1,632	$2,060
Aug-97	63	13	$787	$2,278	$3,065
Sep-97	74	12	$726	$2,666	$3,392
Oct-97	57	11	$665	$2,045	$2,710
Nov-97	58	11	$666	$2,090	$2,756
Dec-97	48	9	$545	$1,741	$2,286
YTD total	706	135	$8,173	$25,628	$33,801

UPDATE:

CMO did not implement this project because they did not have the resources to repackage the leaf into drums.

2.3.6 PROJECT: <u>SD3A RECOVERY</u>

TARGET AREAS:

Recovery of SD3A from VACB, for recycle into VACB

The Environmental Action Plan of 1995 reported that the recovery of SD3A from valacyclovir B step was under evaluation. The current production forecast calls for annual production of 30,000 kg of valacyclovir during 1998, 1999, and 2000. This will generate about 655,000 kg of SD3A (216,000 gallons) annually in the VACB mother liquor and centrifuge wash waste stream (Waste Stream Number 4040). This waste stream is normally discarded to Regular Flammable Waste. The NDA for this process permits recovery of alcohol from the mother liquors and first and second washes for reuse within VACB in place of virgin SD3A in the charge and in the alcohol washes

The project was not pursued during the 1995 - 1997 time frame because of uncertainties regarding both the Greenville Site and the production forecast.

WASTE REDUCTION EXPECTED:

If a recovery (distillation) system recovered 90% of the available alcohol from the waste, for reuse in the process, then the volume of this waste stream would fall from 216,000 gallons per year to 21,600 gallons per year.

CAPITAL AND EXPENSE FUNDS REQUIRED TO COMPLETE THE PROJECT:

- VAC Alcohol Recovery Facility

Estimated Cost	$2,000,000
Scheduled Completion	October 1996

ESTIMATED COST SAVINGS:

The annual cost of the SD3A is $461,000 (at $0.70 per kg) and its value over the three year period is $1,383,000. If the distillation system recovers 90% of the available alcohol, its value would be $1,244,700.

It currently costs $135,000 per year to dispose of this waste stream to the flammable waste incinerators (based on Environmental Operations standard costs). If the recovery left us with only 10% of the waste steam to incinerate, this would cost $13,500 per year for incineration (savings of $365,000 over a three year period.

Total cost savings over a three year period:

Value of alcohol saved:	$1,244,700
Savings in incineration costs:	$365,000
Total savings:	$1,609,700

If the recovery facility would still cost $2,000,000 to construct, this project would pay for itself in two years.

CURRENT SITUATION:

Implementation of this project was explored by the CMO Process Improvement Team. A recycler in Virginia (Dynachem) was audited and approved by Catalytica. However, Dynachem did not come to an agreement for recycle of this alcohol

The CMO Process Improvement Team examined several solvent recyclers and was not successful in finding a solvent recycler which met the acceptability criteria.

2.3.7 PROJECT: RECYCLE OF REJECTED GLASS BOTTLES

TARGET AREAS:

Crusher and Solid Waste Incinerator in ES, SPO and SPD.

WASTE REDUCTION EXPECTED:

See Tables 4 and 5. Most of the glass that is sent to ECVC for recycle comes from rejected vials and bottles (unused), which in the past would have been sent to ES for destruction.

CAPITAL AND EXPENSE FUNDS REQUIRED TO COMPLETE THE PROJECT:

The bottles must be unpacked from their shipping containers, a segregated (clear glass versus colored glass), and repacked into Gaylord cardboard containers (which Catalytica must provide).

ESTIMATED COST SAVINGS:

This endeavor will not save money. The cost of the labor will likely be greater than any savings from hauling crushed glass to the landfill.

CURRENT SITUATION:

Catalytica intends to begin a glass recycling program with EnviroSafe Paints, in Raleigh, NC.

2.3.8 Waste Minimization Indicators within Environment Safety:

In 1997 the Environment Safety Department established the following three indicators, as a tool for measuring our effectiveness in managing the wastes that our sent to us.

Equation #1, for offsite waste shipments:

$$\% \text{ indicator} = \frac{\text{[Total manifested hazardous waste to be destroyed]}}{\text{[Total hazardous waste generated]}}$$

where [Total hazardous waste generated] includes the amount sent from the Drum Storage area for offsite treatment, plus the flammable waste destroyed in the ES incinerators. This indicator does not include any material sent for beneficial recycling or recovery.

Equation #2, for utilization rate of incinerators:

$$\% \text{ indicator} = \frac{\text{[Sum of the actual feedrates to the four liquid waste incinerators]}}{\text{[Sum of the nominal feedrates to the four liquid waste incinerators]}}$$

Equation #3, for non-hazardous waste:

$$\% \text{ indicator} = \frac{\text{[Total amount of non-hazardous waste sent off-site that could have been managed in SWI (this comes from Site Service's monthly report)]}}{\text{[Total amount of non-hazardous waste managed on-site in SWI]} + \text{[Total amount of non-hazardous waste sent off-site that could have been managed in SWI]}}$$

These indicators are calculated monthly by ES, and the monthly figures for 1997 are:

Month	**Hazardous Waste Destruction** (equation #1):			**Non-Hazardous (SWI) Waste** (equation #3):			**Utilization Rate of Liquid Incinerators** (equation #2)		
	Amount of Liquid Waste burned in ES Incinerators, lbs	Total Manifested Hazardous Waste to be Destroyed, lbs	Departmental Indicator, Percent	Amount of non-hazardous Waste managed on-site in the SWI, lbs,	Total Amount of non-Hazardous that went off-site which **could have been** managed in SWI, lbs	Departmental Indicator, Percent	Sum of Actual Feedrates, lb/hr	Sum of Nominal feedrates, lb/hr:	Departmental Indicator, Percent
Jan-97	1,055,745	0	0.0%	637,407	0	0.0%	1,859	2,250	82.6%
Feb-97	1,341,236	1,734	0.1%	430,996	0	0.0%	2163	2,250	96.1%
Mar-97	1,580,338	32,853	2.0%	343,293	20,556	5.6%	2172	2,250	96.5%
Apr-97	1,302,336	0	0.0%	547,022	0	0.0%	2174	2,250	96.6%
May-97	1,564,711	18,022	1.1%	345,230	5,389	1.5%	2080	2,250	92.4%
Jun-97	1,053,863	0	0.0%	275,555	0	0.0%	2059	2,250	91.5%
Jul-97	1,008,808	29,704	2.9%	153,663	0	0.0%	1939	2,250	86.2%
Aug-97	1,351,959	0	0.0%	260,278	0	0.0%	2097	2,250	93.2%
Sep-97	1,316,339	0	0.0%	347,374	10,778	3.0%	2052	2,250	91.2%
Oct-97	1,722,769	0	0.0%	336,541	0	0.0%	2140	2,250	95.1%
Nov-97	1,276,282	0	0.0%	274,437	0	0.0%	2209	2,250	98.2%
Dec-97	1,327,152	20,945	1.6%	262,978	0	0.0%	2251	2,250	100.0%
YTD Totals:	15,901,538	103,258	0.6%	4,214,775	36,722	0.9%	25,195	27,000	93.3%

Targets for 1998:	**Hazardous Waste Destruction Indicator:**	**No greater than 2.0%**
	Non-Hazardous (SWI) Waste indicator:	**No greater than 5%**
	Utilization Rate of liquid Incinerators:	**No less than 90%**

Month	Hazardous Waste Destruction (equation #1):				Non-Hazardous (SWI) Waste (equation #3):				Utilization Rate of Liquid Incinerators (equation #2)			
	Amount of Liquid Waste burned in ES Incinerators, lbs	Total Manifested Hazardous Waste to be Destroyed, lbs	Departmental Indicator, Percent	RATING	Amount of non-hazardous Waste managed on-site in the SWI, lbs,	Total Amount of non-Hazardous that went off-site which **could have been** managed in SWI, lbs	Departmental Indicator, Percent	RATING	Sum of Actual Feedrates, lb/hr	Sum of Nominal feedrates, lb/hr:	Departmental Indicator, Percent	RATING
Jan-98	1,506,018	7,920	0.5%	FEE	335,696	0	0.0%	FEE	2,260	2,250	100.4%	FEE
Feb-98	1,408,696	0	0.0%	FEE	302,074	0	0.0%	FEE	2245	2,250	99.8%	FEE
Mar-98	1,501,399	0	0.0%	FEE	323,369	0	0.0%	FEE	2207	2,250	98.1%	FEE
Apr-98	1,520,226	0	0.0%	FEE	310,834	0	0.0%	FEE	2318	2,250	103.0%	FEE
May-98	1,464,962	28,474	1.9%	EE	305,371	0	0.0%	FEE	2229	2,250	99.1%	FEE
Jun-98	1,274,863	0	0.0%	FEE	271,553	0	0.0%	FEE	2196	2,250	97.6%	FEE
Jul-98	1,094,610	0	0.0%	FEE	173,951	25,889	13.0%	Below Exp.	1681	2,250	74.7%	below expectations
Aug-98	1,278,962	0	0.0%	FEE	270,433	0	0.0%	FEE	2041	2,250	90.7%	ME
Sep-98	1,213,029	25,998	2.1%	Below Exp.	286,007	0	0.0%	FEE	1986	2,250	88.3%	below expectations
Oct-98	1,363,883	0	0.0%	FEE	329,606	0	0.0%	FEE	2213	2,250	98.4%	FEE
Nov-98	1,438,002	0	0.0%	FEE	258,808	0	0.0%	FEE	2099	2,250	93.3%	EE
Dec-98	1,021,117	0	0.0%	FEE	300,768	0	0.0%	FEE	1908	2,250	84.8%	below expectations
YTD Totals:	16,085,767	62,392	0.4%	FEE	3,468,468	25,889	0.7%	FEE	25,383	27,000	94.0%	EE

Below are the monthly indicators for 1999 and 2000

Month	**Hazardous Waste Destruction** (equation #1):				**Non-Hazardous (SWI) Waste** (equation #3):				**Utilization Rate of Liquid Incinerators** (equation #2)			
	Amount of Liquid Waste burned in ES Incinerators, lbs	Total Manifested Hazardous Waste to be Destroyed, lbs	Departmental Indicator, Percent	RATING	Amount of non-hazardous Waste managed on-site in the SWI, lbs,	Total Amount of non-Hazardous that went off-site which **could have been** managed in SWI, lbs	Departmental Indicator, Percent	RATING	Sum of Actual Feedrates, lb/hr	Sum of Nominal feedrates, lb/hr:	Departmental Indicator, Percent	RATING
Jan-99	999,094	0	0.0%	FEE	281,064	2,249	0.8%	FEE	1,504	2,250	66.8%	Below Expectations
Feb-99	1,280,276	55,094	4.1%	Below Expectations	244,352	5,778	2.3%	FEE	1,990	2,250	88.4%	Below Expectations
Mar-99	1,703,863	0	0.0%	FEE	359,956	0	0.0%	FEE	2,296	2,250	102.0%	FEE
Apr-99	1,567,342	0	0.0%	FEE	275,743	11,222	3.9%	EE	2,337	2,250	103.9%	FEE
May-99	1,634,659	0	0.0%	FEE	296,738	23,556	7.4%	Below Expectations	2,232	2,250	99.2%	FEE
Jun-99	1,076,013	19,372	1.8%	ME	313,030	12,500	3.8%	EE	1,871	2,000	93.6%	EE
Jul-99	838,939	26,540	3.1%	Below Expectations	156,350	19,222	10.9%	Below Expectations	2,056	2,250	91.4%	ME
Aug-99	1,248,832	0	0.0%	FEE	224,678	15,889	6.6%	Below Expectations	2,412	2,250	107.2%	FEE
Sep-99	615,842	0	0.0%	FEE	109,877	10,944	9.1%	Below Expectations	1,906	2,000	95.3%	FEE
Oct-99	1,273,960	10,901	0.8%	FEE	215,785	16,818	7.2%	Below Expectations	2,229	2,250	99.1%	FEE
Nov-99	1,630,159	0	0.0%	FEE	216,356	55,727	20.5%	Below Expectations	2,307	2,250	102.5%	FEE
Dec-99	1,687,522	0	0.0%	FEE	300,187	20,682	6.4%	Below Expectations	2,233	2,250	99.2%	FEE
YTD Totals:	15,556,501	111,907	0.7%	FEE	2,994,116	194,587	6.5%	Below Expectations	25,373	26,500	95.7%	FEE

Month	**Hazardous Waste Destruction** (equation #1):				**Non-Hazardous (SWI) Waste** (equation #3):				**Utilization Rate of Liquid Incinerators** (equation #2)			
	Amount of Liquid Waste burned in ES Incinerators, lbs	Total Manifested Hazardous Waste to be Destroyed, lbs	Departmental Indicator, Percent	RATING	Amount of non-hazardous Waste managed on-site in the SWI, lbs,	Total Amount of non-Hazardous that went off-site which **could have been** managed in SWI, lbs	Departmental Indicator, Percent	RATING	Sum of Actual Feedrates, lb/hr	Sum of Nominal feedrates, lb/hr:	Departmental Indicator, Percent	RATING
Jan-00	1,552,653	0	0.0%	FEE	478,762	0	0.0%	FEE	2,304	2,250	102.4%	FEE
Feb-00	1,536,477	12,558	0.8%	FEE	311,022	0	0.0%	FEE	2,217	2,250	98.5%	FEE
Mar-00	1,629,691	0	0.0%	FEE	346,213	3,500	1.0%	FEE	2,195	2,250	97.6%	FEE
Apr-00	1,593,982	0	0.0%	FEE	269,241	0	0.0%	FEE	2,275	2,250	101.1%	FEE
May-00	1,107,168	0	0.0%	FEE	291,775	8,727	2.9%	FEE	1,690	2,250	75.1%	Below Expectations
Jun-00	1,694,530	23,409	1.4%	EE	306,502	3,227	1.0%	FEE	2,419	2,250	107.5%	FEE
Jul-00	1,233,430	0	0.0%	FEE	185,685	0	0.0%	FEE	2,183	2,250	97.0%	FEE
Aug-00	1,611,396	0	0.0%	FEE	246,244	23,136	8.6%	Below Expectations	1,954	2,250	86.8%	Below Expectations
Sep-00	1,331,044	0	0.0%	FEE	283,442	1,455	0.5%	FEE	1,627	2,250	72.3%	Below Expectations
Oct-00	1,581,435	37,970	2.3%	Below Expectations	344,398	27,227	7.3%	Below Expectations	2,058	2,250	91.5%	ME
Nov-00	1,476,823	0	0.0%	FEE	264,410	5,500	2.0%	FEE	2,210	2,250	98.2%	FEE
Dec-00	843,650	0	0.0%	FEE	100,510	30,160	23.1%	Below Expectations	2,061	2,250	91.6%	ME
YTD Totals:	17,192,279	73,937	0.4%	FEE	3,428,204	102,933	3.0%	EE	25,193	27,000	93.3%	EE

PRIMARY ELEMENTS OF THE WASTE MINIMIZATION PROGRAM

PROGRAM ELEMENT	ACTIVITY LEVEL AT CATALYTICA PHARMACEUTICALS, GREENVILLE SITE
TOP MANAGEMENT SUPPORT	
- Corporate Policy	- In place
- Incorporate into annual strategy plan for production	- Not present
- Quantitative or Qualitative goals	- In place
- Waste minimization teams	- In place for CMO
- Waste minimization coordinator	- In place
- Recognition programs	- Not specific to Waste Min. (IFI)
- Training on Waste Minimization techniques	- Undefined
COST ALLOCATION SYSTEM	
- Identify waste management costs	- In place
- Generator Accountability	- Not present
- Compare waste mgt. costs to potential reduction techniques	- In place for CMO, via the Solvent Recovery Team
PERIODIC WASTE MINIMIZATION ASSESSMENTS	
- Identify all points in a process where materials can be prevented from becoming a waste	- Being done in an ongoing basis for existing processes, and is done for potential new processes
- Identify potential waste reduction/recycling techniques applicable to each waste with estimates of capital costs	- Limited to EAP
- Planned schedule of implementing reduction/recycling options	- Limited (EAP)
- Quantitative or qualitative goals as a % of production	- Not present
TECHNOLOGY TRANSFER	- In Place (as new processes are obtained via contracts)
PROGRAM EVALUATION	
- Summary of reduction/recycling efforts	- In place (EAP)
- Review level of progress relative to performance goals	- Not present
- Amendments to the plan	- In place (EAP)
- Documentation of reduction efforts completed or in progress prior to development of plan	- In place (EAP)
ANNUAL SUMMARY (PUBLIC DOCUMENT)	
- Progress vs goals	- Not present

3.0 Background

3.1 Establishment of Waste Minimization Plan at the Greenville Site:

Background:

Refer to the Waste Minimization Plan written in 1998 for a discussion of the history of Waste Minimization at the Greenville Site.