



# CORDEN PHARMA COLORADO, INC.

## ENVIRONMENTAL PROGRAMS STATUS REPORT

May 31, 2019

Pollution Prevention Certifications and Memberships:



**COLORADO INDUSTRIAL  
ENERGY CHALLENGE**  
*Improving Efficiency, Reducing Costs and Emissions*



## **Introduction**

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### **Status Report History and Purpose**

The annual Environmental Programs Status Report (Status Report), which was first issued in 1998, is part of the voluntary pollution prevention program at Corden Pharma Colorado. The Status Report serves as an update to the City of Boulder and Boulder County on the current status and results of Corden Pharma Colorado's pollution prevention activities. The Status Report also meets the requirements of City of Boulder municipal code 10-7.7-8(a)(1). The goal is to provide our stakeholders and the general public with an understanding of Corden Pharma Colorado's environmental footprint. The Status Report also demonstrates Corden Pharma Colorado's commitment to continuous improvement in our operations, both benefitting the patients who depend on the medicines Corden Pharma Colorado produces and also protecting the environment. As always, a copy of the latest Environmental Programs Status Report is available for general public review on our website, [www.cordenpharma.com/facilities/colorado](http://www.cordenpharma.com/facilities/colorado).

### **Status Report Summary**

In 2018, Corden Pharma Colorado increased the production of bulk pharmaceuticals and pharmaceutical intermediates by 64 percent from 2017. As a result, there were negative trends in several environmental figures that directly correlate to production rates. However, because of the different environmental impacts of each process, some environmental figures reflect positive trends due to changes in the mix of products produced and pollution prevention efforts.

From 2017 to 2018, total bulk liquid sent offsite increased by 31 percent, however, the percentage sent offsite for the beneficial purposes of recycling or energy recovery improved from 54 percent to 72 percent. Additional changes from 2017 to 2018 include an 8 percent increase in energy usage and a 60 percent increase in volatile organic compound emissions. Details can be found in the Summary Tables, beginning on page 11.

## **Status Report Outline**

The remainder of this Status Report includes the following sections:

- **2018 Activity Background**
- **Environmental Compliance and Regulatory Status Changes**
- **Pollution Prevention Goals and Objectives**
- **2018 Summary Tables**

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## **2018 Activity Background**

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This section of the Environmental Programs Status Report details the production and technical development activities at Corden Pharma Colorado and the voluntary environmental performance programs in which the company participates.

### **Production Activities Summary**

Corden Pharma Colorado is a member of the Corden Pharma Group. The Corden Pharma Group includes a network of international companies that manufacture bulk intermediates, active ingredients, and final prescription and over-the-counter medicines.

The current focus of Corden Pharma Colorado's activities is the contract production of therapeutic peptides, highly active compounds, and complex small molecules. Corden Pharma Colorado sends the compounds it produces to other manufacturing sites for formulation into finished pharmaceutical products. As a multi-purpose facility that can handle small and large scale production, the medicinal compounds that Corden Pharma Colorado manufactures frequently change in response to market demand and the development of new therapeutic innovations.

### **Technical Development Activities**

Corden Pharma Colorado's technical development activities include designing of manufacturing processes for intermediates and APIs that produce high purity medicinal compounds, while optimizing cost, reliability and safety. These same development activities also have environmental benefits:

- Improving the inherent safety of our manufacturing processes often entails the discovery and development of chemical synthesis routes that minimize or eliminate the use of environmentally undesirable materials.
- The improved synthesis routes that Corden Pharma Colorado scientists design also can help avoid high pressure and high temperature process conditions, with both safety benefits and energy savings.
- Starting with the simplest materials as building blocks for our products and improving the efficiency of our manufacturing processes minimizes the demand for raw materials.
- Maximizing the ability of our existing equipment to manufacture pharmaceutical products minimizes the need to construct and operate new facilities.

Corden Pharma Colorado's technical development facilities include both laboratories for process research and pilot scale production facilities for manufacturing drug compounds in the quantities necessary for approval by regulatory agencies, to supply the clinical trials for new drugs, and to demonstrate new manufacturing processes.

## **Voluntary Environmental Performance Programs**

Corden Pharma Colorado participates in a variety of federal, state, local, and industry-wide initiatives that set challenging pollution prevention standards. The following are the pollution prevention programs in which Corden Pharma Colorado currently participates:

### **City of Boulder Pollution Prevention Program**

Corden Pharma Colorado has been a voluntary participant in the City of Boulder's Pollution Prevention Program since its inception. Participation in the Pollution Prevention Program began with the development of a "Pollution Prevention Master Plan and Statement of Commitments" and the setting of specific pollution reduction goals. Corden Pharma Colorado tracks the success of its environmental initiatives as a founding participant in the Pollution Prevention Program through this annual report to the City of Boulder, now titled "Environmental Programs Status Report."

### **Partners for A Clean Environment**

Corden Pharma Colorado was originally certified under Boulder County's Partners for A Clean Environment (PACE) program in 2001. PACE businesses must meet a stringent list of criteria, demonstrating a sincere commitment to a company-wide pollution prevention program and the implementation of projects that have a quantifiable benefit to the environment.

### **Colorado Environmental Leadership Recognition**

The State of Colorado's Environmental Leadership certification recognizes companies that voluntarily perform above and beyond existing mandated environmental regulations. Environmental Leaders like Corden Pharma Colorado must have a comprehensive and operational environmental management system and a pollution prevention plan that commits the company to a program of continuous environmental improvement. In its letter announcing the Environmental Leadership certification, the Colorado Department of Public Health and Environment thanked Corden Pharma Colorado for the "effort and dedication" it brings to environmental issues. Under the Environmental Leadership program, Corden Pharma Colorado has participated in statewide pollution prevention workshops and mentoring programs. Since 2003, Corden Pharma Colorado has held the highest environmental honor that the State of Colorado bestows, the title of "Gold Level" Environmental Leader.

### **ISO 14001 Certification**

Corden Pharma Colorado obtained certification under the ISO 14001 standard in 2006 and has maintained the certification since that time. Corden Pharma Colorado earned and maintains its ISO 14001 certification through a comprehensive independent audit of the company's environmental, health, safety, and security management system.

## **Colorado Environmental Partnership**

The Colorado Environmental Partnership (CEP) is a membership organization consisting of representatives from the business community, government agencies, and public interest groups. The CEP hosts forums that provide opportunities for members and subject matter experts to discuss topics of mutual interest, share experiences, and recognize environmental achievements. The Colorado Environmental Partnership also collaborates with organizations that share its goals in hosting public events for business audiences on a range of topics related to environmental performance and sustainability.

## **Colorado Industrial Energy Challenge**

In 2010, Corden Pharma Colorado became a Charter Member of the Colorado Industrial Energy Challenge (CIEC) program. CIEC is a voluntary program sponsored by the Colorado Energy Office (CEO) and the U.S. Department of Energy (DOE). The program challenges industrial firms to set energy efficiency goals and to demonstrate progress towards achieving their goals. Corden Pharma Colorado was awarded an “Excellence in Energy Efficiency” award in 2012, and again in 2017, for its energy reduction efforts.

## **Volunteer Work with Boulder County Parks and Open Space**

Corden Pharma Colorado has been supporting Boulder County Open Space (BCOS) since 2009. Each year, Corden Pharma Colorado employee volunteers, along with their friends and families, have spent a day or two working to maintain and improve various open spaces. Employees have built fences, repaired trails, collected native seeds, fixed bridges, restored burned slash pile areas, removed infected trees, and worked on whatever else might be needed. In 2018, Corden worked at Heil Valley Ranch in July and October to assist in straightening existing fences that had fallen into disrepair, building new fences, and removing unneeded fencing and barbed wire. This is part of an effort by BCOS to improve the existing site infrastructure on a recently acquired piece of property from the Heil family that is now part of BCOS. In 2019, Corden will again be supporting BCOS at locations to be determined.

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## **Environmental Compliance or Regulatory Status Changes**

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There was no change in Corden Pharma Colorado's compliance or regulatory status in 2018.

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## Pollution Prevention Goals and Objectives

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Corden Pharma Colorado is committed to pursuing pollution prevention goals associated with our energy reduction, process waste minimization, and other pollution prevention efforts. This section details the progress Corden Pharma Colorado made in 2018 towards these three goal categories, including specific program achievements and plans for further action in 2019 and 2020.

### Energy Reduction Goals

Due to recent increases in energy demand driven by facility improvements and growth of the business, energy reduction has been a challenge. From 2017 to 2018, the company increased onsite energy consumption by 8 percent. However, energy consumption at Corden Pharma Colorado has decreased 21 percent since 2005 when the company's original energy goals were set.

Corden Pharma Colorado continues to identify, evaluate, and implement energy reduction measures. A number of initiatives have been completed over the last ten years that were highly effective. The following objectives are underway to continue to support energy reduction both on and off site:

Objective 1a: Implement a new standard for lighting in office and manufacturing buildings, where LED lights will be used in new installations. This will result in lower energy consumption.

*Achievement:* Corden Pharma Colorado has implemented the new lighting standard and over the last several years has installed several dozen LED lights for specific applications to collect data on performance and functionality. In 2018, in the office areas, the T-8 lighting system replacement program progressed. A keystone Smart Drive LED system is being utilized that allows direct replacement into ballasted systems. Assuming 25% utilization, this saves 20 kilowatt-hour per year per bulb. This allows the changeover to continue with minimal disruption to the office areas.

Objective 1b: A new larger lyophilizer is being installed to expand production capability. Rather than installing a new independent chiller unit to cool the lyophilizer, a new dedicated pipe will be installed from the existing cooling tower to the new lyophilizer to provide energy efficient cooling. This will eliminate the need for a new 95 ton chiller.

*Achievement:* This unit has been designed. Installation has begun and will be completed in 2019.

Objective 1c: To meet production needs, one manufacturing area in Plant 3 is being converted to conform to ISO 8 cleanroom standards. In this area, Corden Pharma Colorado will replace an existing HVAC unit. Overall capacity will increase with dual units due to implementation of the ISO



8 cleanroom standards and replacement of swamp cooling with Dx cooling. To mitigate the effect of this capacity increase, the dual replacement air conditioning units will be controlled by Variable Frequency Drives (VFD) and will utilize multiple service modes to allow reduced usage during non-active production periods. Additionally, LED lighting will be installed, and active pressure control will be installed to ensure that sufficient but not excess conditioned air is utilized.

*Achievement:* Design complete and the majority of the equipment installed. The project is currently in the commissioning phase.

## Process Waste Minimization Goals

Corden Pharma Colorado strives to reduce the solvent waste and air emissions its pharmaceutical manufacturing processes generate. The company achieves these goals by modifying manufacturing processes to reduce the need for production material, recycling materials for re-use, controlling air emissions, and many other process waste minimization efforts. Over the years, Corden Pharma Colorado has successfully reduced the process waste from many manufacturing steps. The following specific objectives were identified to further advance these efforts in 2018 and 2019.

Objective 2a: Eliminate the use of holding drums in the chromatography steps of a manufacturing process by instead storing the intermediate products in a vessel between steps. This will eliminate the waste of approximately 90 drums per batch and also reduce the air emissions generated from charging the material to drums and then back into a vessel.

*Achievement:* Complete. The process improvements were implemented in 2019.

Objective 2b: Evaluate a manufacturing process for optimization and yield improvement, which will result in reduced raw material usage, air emissions, and waste generation per mass of product produced.

*Achievement:* Complete. In 2017, the manufacturing process was optimized, eliminating one recrystallization purification step and improving the yield by 32 percent. The savings from this optimization were fully realized in 2018.

Objective 2c: Evaluate three solvent waste streams in a specific manufacturing process for on-site recycle. Heptane, MTBE, and ethyl acetate, which are used in a manufacturing process, will be evaluated for recycling feasibility and implemented if possible.

*Achievement:* Laboratory studies and engineering evaluations have been completed. Ethyl acetate is likely a viable solvent recycle operation for this process, and the recovery will be demonstrated in the plant in 2019, targeting approximately 40 percent solvent recycle via

packed column separation. MTBE and heptane will require more development work to determine viability.

Objective 2d: Evaluate two solvent waste streams in a specific manufacturing process for on-site or off-site recycle. DMF and acetonitrile, which are used in a manufacturing process, will be evaluated for recycling feasibility during the scale-up of this process.

*Achievement:* Engineering evaluations have been completed, as well as evaluation of off-site recycling. Acetonitrile will be recycled on-site in this process, and this recovery will be demonstrated in the plant in 2019. DMF will require more development work to determine viability.

Objective 2e: Evaluate one process manufacturing step for a reduction in acetonitrile usage. If viable, the target will be a 50 percent reduction in acetonitrile usage in this step of the process.

### **Other Pollution Prevention Goals**

In addition to the energy efficiency and process waste minimization efforts listed above, Corden Pharma Colorado also set the following additional pollution prevention goal:

Objective 3a: Reduce paper usage by electronically managing some business records that the company currently prints on paper.

*Achievement:* Corden Pharma Colorado has previously converted several document types to electronic files. Corden Pharma Colorado is currently working on a multi-year implementation of an electronic data management system to convert additional records and forms to electronic storage.

### **Other Pollution Prevention Activities**

The following activities represent additional efforts to prevent pollution in 2017 and 2018:

- Corden Pharma Colorado employees participated in the Boulder County Clean Air Consortium Summer Clean Air Challenge.

In addition to the projects and plans mentioned above, all Corden Pharma Colorado process teams continue to identify and evaluate pollution prevention opportunities in their areas of expertise. The Pollution Prevention Team supports and tracks all pollution prevention efforts at Corden Pharma Colorado, with a focus on reducing energy consumption and solvent usage and increasing solvent recovery in production processes.

## 2018 Summary Tables

### 2018 Production at Corden Pharma Colorado

In 2018, as measured by mass, Corden Pharma Colorado increased the production of bulk pharmaceuticals and pharmaceutical intermediates by 64 percent from 2017. At the same time, the company's raw materials usage also increased by 7 percent. The environmental figures below reflect the result of both Corden Pharma Colorado's production changes as well as the company's implementation of pollution prevention measures.

### Water Usage

The following table details water use at Corden Pharma Colorado.

Type of Usage	2014 (gallons)	2015 (gallons)	2016 (gallons)	2017 (gallons)	2018 <sup>1</sup> (gallons)
Process	18,807,328	18,899,536	19,019,464	20,893,779	17,414,096
Commercial	1,637,228	1,747,121	1,655,609	1,838,633	1,930,145
Cooling	9,683,469	8,557,277	7,853,316	8,230,401	10,221,153
Irrigation	1,543,400	1,494,764	1,459,250	1,587,350	1,513,788
<b>Total</b>	<b>31,671,425</b>	<b>30,698,698</b>	<b>29,987,639</b>	<b>32,550,163</b>	<b>31,079,183</b>

<sup>1</sup> Total water flow for 2018 was not available due to a failure of the City Water meter. 2018 usage was estimated using the average of 2015-2017 data.

### Wastewater Pretreatment Plant Discharge

Corden Pharma Colorado sends aqueous wastes from production activities through its onsite pretreatment facility. Wastewater leaving the system is discharged to the City of Boulder treatment facility. The following table lists the major components of the wastewater that Corden Pharma Colorado discharges to the City of Boulder treatment facility:

	Discharge (in Pounds unless otherwise indicated)					
	1995 (Baseline)	2014	2015	2016	2017	2018
Volume, gal	21,035,000	9,865,603	8,890,417	7,378,314	8,752,348	9,720,383
Total Organic Content (TOC)	115,000	9,541	6,906	3,673	3,878	6,504
Chromium	31	3.8	1.6	1.3	1.0	1.1
Copper	4.3	16.4	12.2	16.6	10.4	11.2
Lead	2.8	4.1	3.7	3.1	3.6	0.0
Nickel	4.1	2.9	2.3	1.8	2.6	2.9
Zinc	73	72.1	43.2	55.6	40.0	51.7

### **Bulk Liquid Sent Offsite - Waste Disposal and Recycling**

The following values represent the amount of material Corden Pharma Colorado sent offsite in bulk quantities for recycling, energy recovery, or incineration. Due to an increase in production, a change in production mix, and the different solvents required for each product, from 2017 to 2018, the total bulk liquid sent offsite increased by 31 percent, but bulk liquid sent offsite per unit of product produced decreased by 20 percent. The percentage sent offsite for the beneficial purposes of recycling or energy recovery improved from 54 percent to 72 percent.

<b>Description</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
Total bulk liquid sent offsite (kg)	5,222,723	2,349,820	1,704,338	2,587,731	3,401,666
% Change from previous year	+159%	-55%	-27%	+52%	+31%
% Sent offsite for recycling	53.7%	1%	0%	1%	0%
% Sent offsite for energy recovery	45.9%	98%	71%	53%	72%

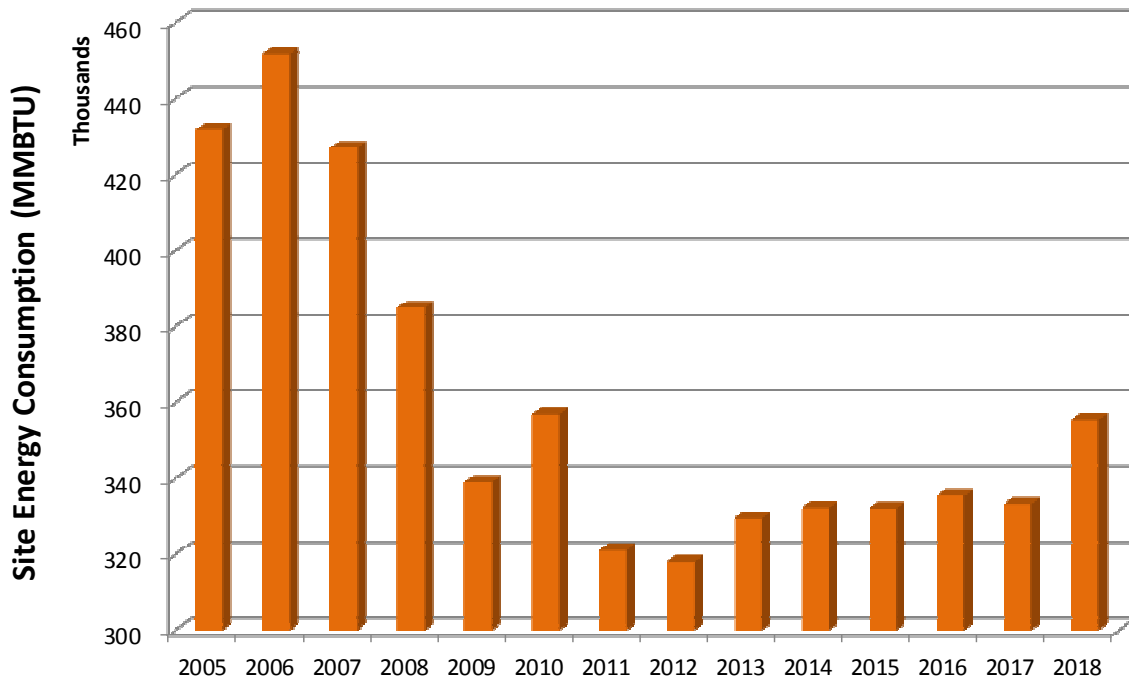
## Energy Consumption

The following table presents the standard energy metrics of natural gas and electricity consumption at Corden Pharma Colorado. Additionally, off-site nitrogen consumption converted to energy equivalents is also presented since it has been a focus area for the company, and since it has a positive impact on global energy consumption. From 2017 to 2018, both natural gas and electricity usage increased.

Energy Type	2014	2015	2016	2017	2018
Natural Gas (therms)	1,199,737	1,128,570	1,135,760	1,083,400	1,180,350
Electricity (KWH)	21,226,316	21,922,788	22,469,916	22,484,035	23,735,366
Off-site Nitrogen (KWH equivalent)	4,752,131	4,009,166	2,377,549	3,146,304	3,675,456

Energy reduction has been a priority at Corden Pharma Colorado for many years. A number of initiatives have been completed over the last several years that were highly effective as shown in the following graph:

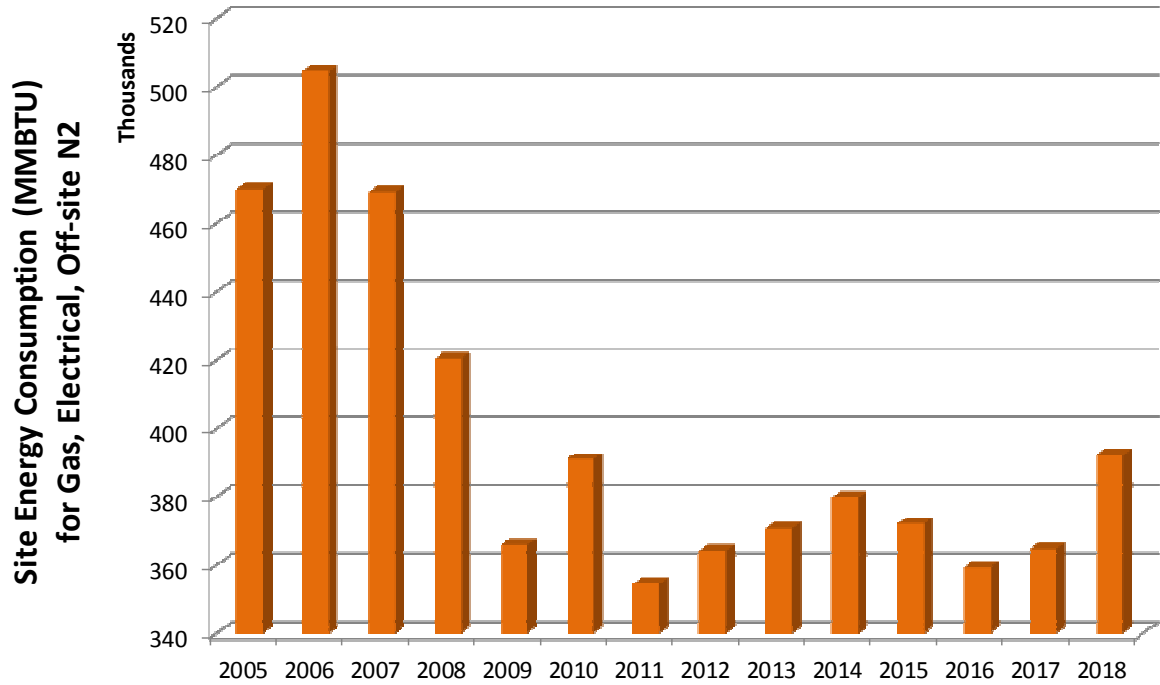
**Combined Onsite Energy Use  
(Electricity & Natural Gas)**



NOTE: Electricity unit conversions made using Colorado Industrial Energy Challenge methodology, accounting for typical coal plant thermal efficiency.

Additionally, when the graph is updated to include the energy used offsite to produce nitrogen for the site, Corden Pharma Colorado's nitrogen use reduction efforts, especially in 2015 and 2016, are shown to have a positive impact on global energy use:

Combined Onsite and Offsite Energy Use  
(Electricity, Natural Gas, & Offsite Nitrogen Energy Equivalents)



NOTE: Electricity unit conversions made using Colorado Industrial Energy Challenge methodology, accounting for typical coal plant thermal efficiency.

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## Air Emissions

The following table displays Corden Pharma Colorado's air emissions, divided into Toxic Release Inventory (TRI) compounds, Hazardous Air Pollutants (HAPs), and Volatile Organic Compounds (VOCs). From 2017 to 2018, overall VOC emissions increased by 60 percent and HAP emissions increased by 33 percent. An overall increase in production resulted in the increase.

	1989 (Baseline)	2015	2016	2017	2017	2018
Acetone <sup>3</sup>	242,500	490	1,400	3,200	3,700	5,200
Acetonitrile <sup>1,2</sup>	--	2,460	2,600	2,100	2,700	5,100
Dimethylformamide <sup>1,2</sup>	--	70	130	150	190	280
1,4-Dioxane <sup>1,2</sup>	--	--	60	260	250	620
Hexane <sup>1,2</sup>	36,600	2,800	2,600	1,400	950	100
Hydrochloric acid <sup>1</sup>	4,000	420	160	190	160	160
Methanol <sup>1,2</sup>	109,600	6,100	9,100	4,900	4,790	6,000
Methyl chloride <sup>1,2</sup>	6,700	--	--	--	--	--
n-Methyl-2-pyrrolidinone <sup>2</sup>	--	50	10	7	3	40
Methyl Tert-Butyl Ether <sup>1,2</sup>	--	4,310	4,230	680	1060	1,750
Methylene chloride <sup>1</sup>	103,300	5,150	1,840	1,230	850	1,270
Pyridine <sup>2</sup>	--	42	2	3	0	1
Toluene <sup>1,2</sup>	284,400	483	550	240	220	730
Triethylamine <sup>1,2</sup>	--	--	3	19	20	30
<b>Total TRI air emissions (tons)</b>	<b>375</b>	<b>11</b>	<b>11</b>	<b>5</b>	<b>6</b>	<b>8</b>
<b>% change from previous year</b>	--	<b>-15%</b>	<b>0%</b>	<b>-55%</b>	<b>+20%</b>	<b>+33%</b>
<b>% change from 1989</b>	--	<b>-97%</b>	<b>-97%</b>	<b>-99%</b>	<b>-98%</b>	<b>-98%</b>

<b>Total HAP emissions (tons)</b>	<b>293</b>	<b>11</b>	<b>11</b>	<b>6</b>	<b>6</b>	<b>8</b>
<b>% change from previous year</b>	--	<b>-15%</b>	<b>0%</b>	<b>-45%</b>	<b>0%</b>	<b>+33%</b>
<b>% change from 1989</b>	--	<b>-96%</b>	<b>-96%</b>	<b>-98%</b>	<b>-98%</b>	<b>-97%</b>

<b>Total VOC emissions (tons)</b>	<b>490</b>	<b>12</b>	<b>13</b>	<b>8</b>	<b>10</b>	<b>16</b>
<b>% change from previous year</b>	--	<b>-25%</b>	<b>+8%</b>	<b>-38%</b>	<b>+25%</b>	<b>+60%</b>
<b>% change from 1989</b>	--	<b>-98%</b>	<b>-97%</b>	<b>-98%</b>	<b>-98%</b>	<b>-97%</b>

<sup>1</sup> These chemicals are also classified as HAPs and are included in the HAP total above.

<sup>2</sup> These chemicals are also classified as VOCs and are included in the VOC total above.

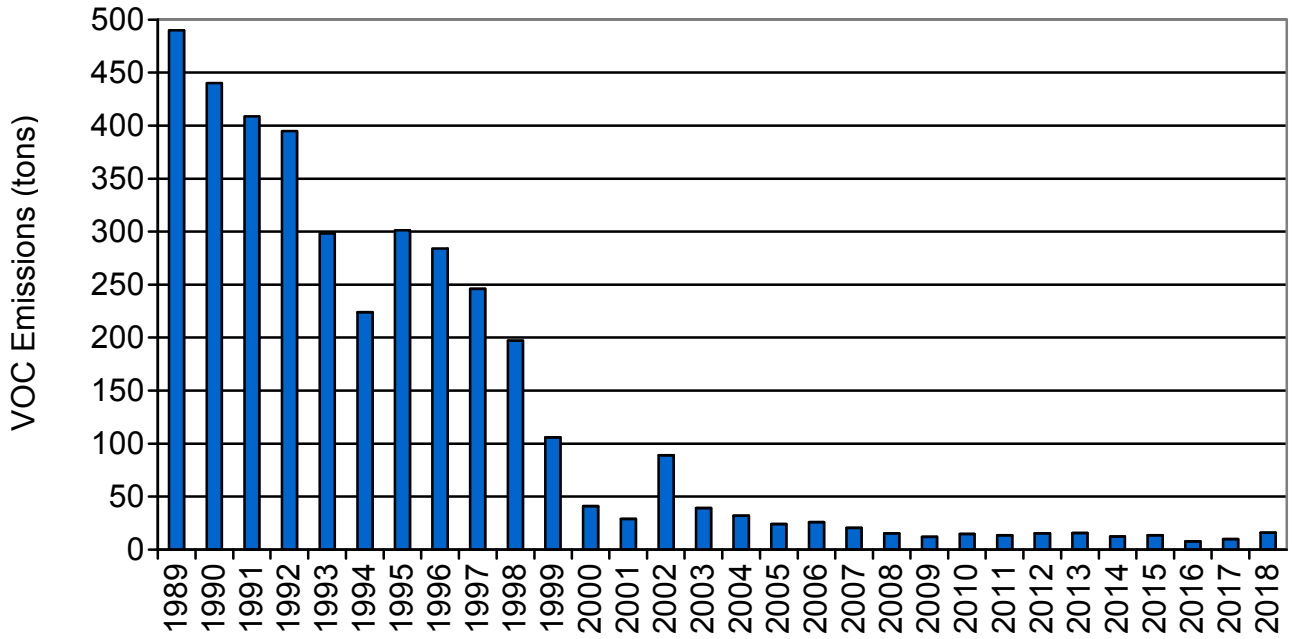
<sup>3</sup> Acetone is no longer included in TRI. It is also no longer classified as a VOC. After 1996, it is not included in the VOC total.

<sup>4</sup> Shaded blocks indicate that TRI reporting for that chemical was not required during that year. They are not included in the TRI emissions total.

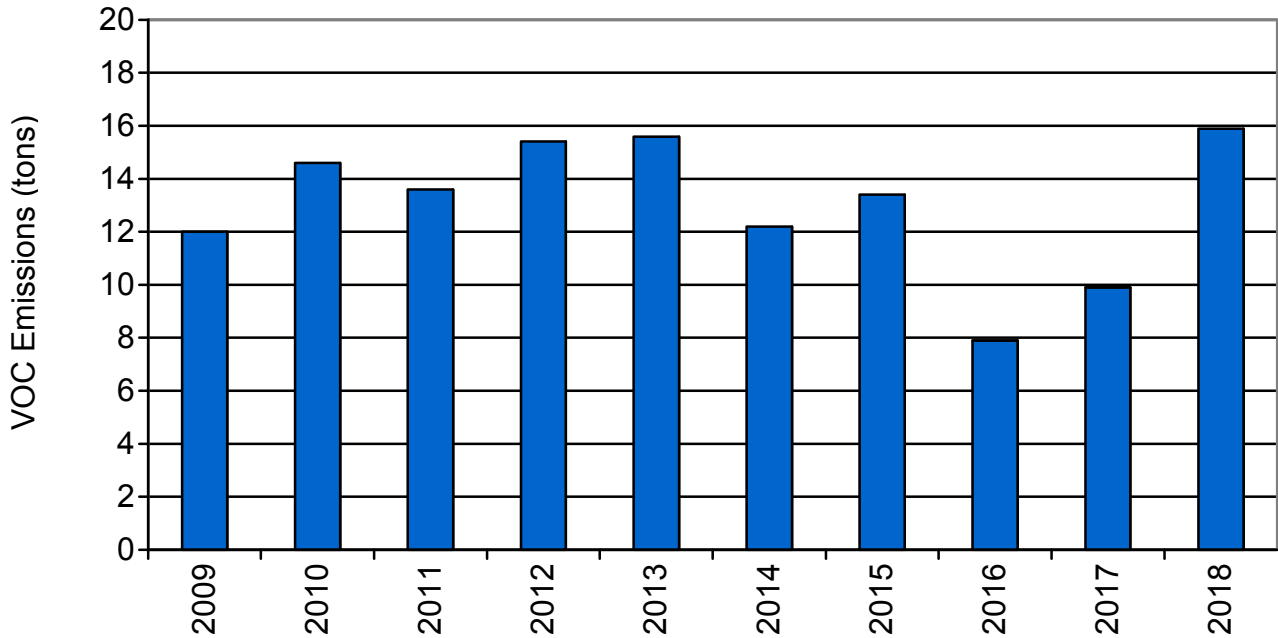
HAP = Hazardous Air Pollutant

VOC = Volatile Organic Compound

### Volatile Organic Compounds (VOC) Air Emissions Trend, since 1989



### Volatile Organic Compounds (VOC) Air Emissions Trend, Last 10 Years





## General Waste Recycling

In 2018, Corden Pharma Colorado recycled a considerable amount of general waste. The totals presented here do not include recycling of removed manufacturing equipment. In 2018, Corden Pharma Colorado recycled about 60,000 pounds of office paper, shredded documentation, newspaper, cardboard, magazines, and phone books. These efforts helped Corden Pharma Colorado save an estimated 520 trees from destruction.

Type of Material	Pounds Recycled
Paper and Cardboard	60,000
Metals	1,100
Plastic	2,100
Compost	~10,000