

COMMONWEALTH OF PENNSYLVANIA  
DEPARTMENT OF ENVIRONMENTAL PROTECTION  
FIELD OPERATIONS - BUREAU OF AIR QUALITY

OPERATING PERMIT

In accordance with provisions of the Air Pollution Control Act, the act of January 8, 1960, P.L. 2119, as amended, and after due consideration of an application received under Chapter 127 of the rules and regulations of the Department of Environmental Protection, the Department hereby issues this permit for the operation of the air contamination source(s) described below:

Permit No.	<u>OP-46-0035</u>	Source(s)	<u>NOx/VOC Sources</u>
Owner	<u>SmithKline Beecham Pharmaceuticals</u>	Air	<u></u>
Address	<u>709 Swedeland Road</u>	Cleaning	<u></u>
	<u>King of Prussia, PA 19406</u>	Device	<u></u>
Attention	<u>Eileen D. Hotte, Ph.D.</u>	Location	<u>Upper Merion Township</u>
	<u>Manager, Radiation &amp; Environmental Safety</u>		<u>Montgomery County</u>

This permit is subject to the following conditions:

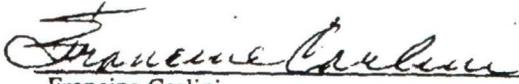
1. That the source(s) and any associated air cleaning devices are to be:
  - a. operated in such a manner as not to cause air pollution;
  - b. operated and maintained in a manner consistent with good operating and maintenance practices.
2. This permit is valid only for the specific equipment, location and owner named above.

(SEE ADDITIONAL CONDITIONS ATTACHED)

Failure to comply with the conditions placed on this permit is a violation of Section 127.444. Violation of this or any other provision of Article III of the rules and regulations of the Department of Environmental Protection will result in suspension or revocation of this permit and/or prosecution under Section 9 of the Air Pollution Control Act.

Issued 03/27/1997

Expires ~~03/27/2002~~

  
Francine Carlini  
Regional Manager  
Air Quality

cc: Central Office  
Administration  
SEFO  
Re (KAL)92.8

**OPERATING PERMIT CONDITIONS**  
**PERMIT NO. OP-46-0035**  
**SMITHKLINE BEECHAM PHARMACEUTICALS**  
(REVISED 10/20/1998)

**CONDITIONS (continued):**

3. A. This Operating Permit, OP-46-0035 is issued to SmithKline Beecham Pharmaceuticals for the operation of oxides of nitrogen (NOx) and volatile organic compounds (VOCs) emission sources regulated under 25 Pa. Code Sections 129.91 - 129.95. With the exception of the source listed in Condition 7 below, this Operating Permit, OP-46-0035, also specifies SmithKline Beecham Pharmaceuticals Reasonably Available Control Technology (RACT) requirements for sources of VOCs and NOx.

Other pollutants are regulated under the applicable provisions of Title 25 of the Pennsylvania Code and by existing permit conditions which are incorporated by reference.

- B. The expiration date shown on the Operating Permit, OP-46-0035, is for state purposes only. For Federal enforcement purposes the Operating Permit shall remain in effect as part of the Pennsylvania State Implementation Plan (SIP) until repealed pursuant to 40 CFR 51 and approved by the United States Environmental Protection Agency (EPA). The Operating Permit shall become enforceable by the EPA upon its approval of the above as a revision to the SIP.
- C. The company shall not impose conditions upon or otherwise restrict the Department's access to the aforementioned source(s) and shall allow the Department to have access at any time to said source(s) with such measuring and recording equipment, including equipment for recording visual observations, as the Department deems necessary and proper for performing its duties and for the effective enforcement of the Air Pollution Control Act.
- D. If at any time the Department has cause to believe that air contaminant emissions from the aforementioned source may be in excess of the limitations specified in, or established pursuant to, any applicable rule or regulation contained in Article III of the Rules and Regulations of the Department of Environmental Protection, the company shall be required to conduct whatever tests are deemed necessary by the Department to determine the actual emission rate(s). Such testing shall be conducted in accordance with the provisions of Chapter 139 of the Rules and Regulations of the Department of Environmental Protection, where applicable, and in accordance with any restrictions or limitations established by the Department at such time as it notifies the company that testing is required.
- E. SmithKline Beecham Pharmaceuticals shall maintain comprehensive records for all de-minimus sources, in a Department approved format, to demonstrate compliance with the de-minimus limits.

OPERATING PERMIT CONDITION  
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(REVISED 10/20/1998)

**CONDITIONS (continued):**

F. This RACT determination applies to the emissions of NOx and VOC pollutants only. Emissions of other pollutants, including criteria pollutants, shall be governed by existing plan approvals, operating permits, and the applicable requirements of the Rules and Regulations of the Department. Such approvals, permits and requirements are incorporated herein by reference and made part of this permit. All conditions from plan approvals and operating permits No. 46-302-053, 46-301-216A, 46-301-221, 46-301-240, 46-301-313, 46-313-113, 46-313-103, 46-313-112, 46-313-115, 46-399-098 and 46-312-021 are incorporated in this permit. The referenced plan approvals and operating permits will no longer be issued separately in the future. If any conflict arises between the conditions of this permit and the referenced plan approvals and operating permit, the more stringent requirements shall apply.

4. Hours of Operation

- A. The hours of operation of the sources listed in Appendix A as Emergency Generators shall be limited to less than 500 hours per year in a 12 month consecutive period, except that Biopharm, UM-40 Emergency Generator (No. 0471) shall be operated no more than 200 hours in a 12-month consecutive period.
- B. For the sources listed in Appendix A as the Boilers and Pathological Incinerators their hours of operation shall not be limited.

5. RACT Implementation

A. The following conditions apply to the No. 2 & 3W boilers.

- 1. Boilers No. 2 & 3W shall be derated from a rated heat input of 51 MMBtu/hr to a rated heat input of 49 MMBtu/hr by the installation of the following:
  - a. Flow transmitters on the existing natural gas orifice plates.
  - b. A modification of the flow control valve so that the natural gas supply does not exceed 49,000 ft<sup>3</sup>/hr.
  - c. A high alarm so that a warning will be supplied when the natural gas flow rate reaches 48,000 ft<sup>3</sup>/hr.
  - d. The flow rate of No. 6 fuel oil shall be limited to 327 gallons per hour.
- 2. RACT shall be an annual tune-up on the combustion process for Boilers No. 2 & 3W.

EXISTING PERMIT CONDITION  
**PERMIT NO. OP-46-0035**  
**SMITHKLINE BEECHAM PHARMACEUTICALS**  
(REVISED 10/20/1998)

**CONDITIONS (continued):**

- a. Inspection, adjustment, cleaning or replacement of fuel burning equipment, including the burners and moving parts necessary for proper as specified by the manufacturer.
  - b. Inspection of the flame pattern or characteristics and adjustments necessary to minimize total emissions of NO<sub>x</sub>, and, to the extent practicable, minimize the emissions of CO.
  - c. Inspection of the air-to-fuel ratio control system and adjustments necessary to ensure proper calibration and operation as specified by the manufacturer.
3. Each adjustment conducted under the procedures in Condition (5)(A)(1) shall be recorded in a permanently bound log book.
- a. The date of the tuning procedure.
  - b. The name of the service company and technicians.
  - c. The final operating rate or load.
  - d. The final CO and NO<sub>x</sub> emission rates.
  - e. The final excess oxygen rate.
4. Emissions of volatile organic compounds (VOCs) shall be minimized by annual combustion tuning and/or good operating practices.
5. The initial tune-up on the combustion process shall be performed by May 31, 1996. Subsequent combustion tune-ups shall be performed annually.
6. The annual adjustment shall be made in accordance with the EPA document "Combustion Efficiency Optimization Manual for Operators of Oil and Gas-fired Boilers," September 1983 (EPA-340/1-83-023) or equivalent procedures approved in writing by the Department.

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SMITHKLINE BEECHAM PHARMACEUTICALS  
(REVISED 10/20/1998)

**CONDITIONS (continued):**

B. The following conditions apply to:

Boiler 1  
Boiler 2  
Boiler 9  
Boiler 15  
Boiler 4W  
Boiler 3W  
Boiler 10  
Boiler 11  
Boiler 14  
Boiler 44  
Boiler 45

1. RACT shall be an annual tune-up on the combustion process for the units listed in Condition 5.B.
  - a. Inspection, adjustment, cleaning or replacement of fuel burning equipment, including the burners and moving parts necessary for proper operation as specified by the manufacturer.
  - b. Inspection of the flame pattern or characteristics and adjustments necessary to minimize total emissions of NO<sub>x</sub>, and, to the extent practicable, minimize the emissions of CO.
  - c. Inspection of the air-to-fuel ratio control system and adjustments necessary to ensure proper calibration and operation as specified by the manufacturer.
    - (1) Each adjustment conducted under the procedures in Condition 5.B(1) shall be recorded in a permanently bound log book.
      - (a) The date of the tuning procedure.
      - (b) The name of the service company and technicians.
      - (c) The final operating rate or load.
      - (d) The final CO and NO<sub>x</sub> emission rates.
      - (e) The final excess oxygen rate.

**OPERATING PERMIT CONDITION**  
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**SMITHKLINE BEECHAM PHARMACEUTICALS**  
(REVISED 10/20/1998)

**CONDITIONS (continued):**

- (2) Emissions of volatile organic compounds (VOCs) shall be minimized by annual combustion tuning and/or good air pollution control practices.
  - (3) The initial tune-up on the combustion process shall be performed by May 31, 1996. Subsequent combustion tune-ups shall be performed annually.
  - (4) The annual adjustment shall be made in accordance with the EPA document "Combustion Efficiency Optimization Manual for Operators of Oil and Gas-fired Boilers," September 1983 (EPA-340/1-83-023) or equivalent procedures approved in writing by the Department.
2. Boilers 44 & 45 shall be equipped with low NOx burners with flue gas recirculation (FGR).
  3. The total amount of No. 2 fuel oil fired in Boilers 44 & 45 shall not exceed 478, 286.0 gallons in a twelve (12) month rolling average.
  4. Nitrogen oxides (NOx) emissions from the boilers shall not exceed 30 ppm corrected to 3% O<sub>2</sub> content when firing natural gas, and 140 ppm corrected to 3% O<sub>2</sub> content when firing No. 2 fuel oil, and 8.2 Tons in a twelve (12) month rolling average
- C. The following conditions apply to Boilers 5, 6, 7 and 8, Pathological Waste Incinerator, Building 3; Pathological Waste Incinerator, Building 21; Pathological Waste Incinerator, Building 26; and all sources listed in Appendix A as Emergency Generators.
1. The combustion sources and units listed above shall be installed, maintained, and operated in accordance with manufacturers specifications.
  2. The combustion sources and units listed above shall also be operated and maintained in accordance with good air pollution control practices.
- D. The company shall paint all six (V-301 - V-306) with white paint or install new pressure relief vents on the ethyl acetate tank by May 31, 1996.

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**CONDITIONS (continued):**

6. Recordkeeping/Monitoring Requirements

- A. A bound logbook (or other Department approved method) for each source listed in Appendix A will be kept and sufficient data recorded so that compliance with Conditions 4 through 6 can be determined. Records shall be kept for a minimum of two (2) years and shall be made available to the Department upon request.
- B. For boilers Nos. 5, 6, 7, 8, 12, 13, 14, 15, 44, and 45 the following records shall be kept.
1. A certification from the fuel supplier of the type of fuel delivered.
  2. A certification that the fuel complies with ASTM D396-78 "Standard Specifications for Fuel Oils."
  3. Boilers 44 and 45 are subject to Subpart Dc of the Standards of Performance for New Stationary Sources and shall comply with all applicable requirements of this Subpart. 40 CFR § 60.4 requires submission of copies of all requests, reports, applications, submittals, and other communications to both EPA and the Department. The EPA copies shall be forwarded to:  
  
Director  
Air, Toxics and Radiation Division  
U.S. EPA, Region III  
841 Chestnut Street  
Philadelphia, PA 19107
- C. For boilers No. 1, 2, 3W, 4W, 9, 10, 11 and 14 the following records shall be kept.
1. A certification from the fuel supplier of the type of fuel delivered.
  2. A certification from the fuel supplier of the nitrogen content of the fuel and identification of the sampling method and sampling protocol.
- D.
1. The company will monitor and record the numbers of batches of each product manufactured or processes performed in the antibiotic manufacturing facility.
  2. The company will monitor and record the number of each unit operation performed in each of the pilot development laboratories.
  3. The company will keep records of the amount of waste transferred at each of the five hazardous waste transfer areas.

**ERATING PERMIT CONDITION**  
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**SMITHKLINE BEECHAM PHARMACEUTICALS**  
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**CONDITIONS (continued):**

4. The company shall monitor and record the total combined fuel use in all the fuel oil storage tanks. Fuel use will be monitored through the use of purchasing records.
5. SB proposes to monitor and record the total throughput through each of the raw material storage tanks and solvent waste storage tanks operated in the antibiotic manufacturing facility tank farm. Raw material throughput will be monitored through the use of purchasing records and solvent waste throughput will be monitored through the use of hazardous waste manifests.

Operating Conditions for New Sources incorporated into this Operating Permit

7. The following conditions incorporated from Plan Approval PA-46-0035A apply to the emergency generator in Building 4.
  - A. The Company shall limit the NO<sub>x</sub> emissions to less than 4.0 tons/yr.  
  
This limit shall be verified by the amount of No. 2 fuel oil used.
  - B. The Company shall limit the total amount of No. 2 fuel oil to 17,000 gallons per year, and 0.2% sulfur.
  - C. The opacity from the engine covered under this Operating Permit shall not exceed the following:
    - a. Equal to or greater than 20% for a period or periods aggregating more than three minutes in any one hour.
    - b. Equal to or greater than 60% at any time.

(SMC98)196-6

**PERATING PERMIT CONDITION**  
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**SMITHKLINE BEECHAM PHARMACEUTICALS**  
(REVISED 10/20/1998)

**CONDITIONS (continued):**

**APPENDIX A**

**Identity and Location of NOx Sources**

<b>Source Description</b>	<b>Manufacturer and Model Number</b>	<b>Fuel Used Capacity (MMBtu/hr)</b>	
Boiler No. 1	Cleaver Brooks	Natural Gas/No. 6 Fuel Oil	25.0
Boiler No. 2	Cleaver Brooks	Natural Gas/No. 6 Fuel Oil	51.0
Boiler No. 3W	Cleaver Brooks	Natural Gas/No. 6 Fuel Oil	51.0
Boiler No. 4W	Cleaver Brooks	Natural Gas/No. 6 Fuel Oil	25.0
Boiler No. 5	Cleaver Brooks	Natural Gas/No. 2 Fuel Oil	10.461
Boiler No. 6	Cleaver Brooks	Natural Gas/No. 2 Fuel Oil	10.461
Boiler No. 7	Cleaver Brooks	Natural Gas/No. 2 Fuel Oil	10.461
Boiler No. 8	Cleaver Brooks	Natural Gas/No. 2 Fuel Oil	10.461
Boiler No. 9	Cleaver Brooks	Natural Gas/No. 6 Fuel Oil	34.482
Boiler No. 10	Cleaver Brooks	Natural Gas/No. 6 Fuel Oil	34.482
Boiler No. 11	Cleaver Brooks	Natural Gas/No. 6 Fuel Oil	34.482

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 (REVISED 10/20/1998)

**CONDITIONS (continued):**

**APPENDIX A**

**Identity and Location of NO<sub>x</sub> Sources**

Source Description	Manufacturer and Model Number	Fuel Used Capacity (MMBtu/hr)	Capacity (kW)
Boiler No. 12	Kewanee	Natural Gas/No. 2 Fuel Oil	2.05
Boiler No. 13	Kewanee	Natural Gas/No. 2 Fuel Oil	2.05
Boiler No. 14	Cleaver Brooks	Natural Gas/No. 2 Fuel Oil	25.106
Boiler No. 15	Cleaver Brooks	Natural Gas/No. 2 Fuel Oil	25.106
Boiler No. 44	Cleaver Brooks	Natural Gas/No. 2 Fuel Oil	33.48
Boiler No. 45	Cleaver Brooks	Natural Gas/No. 2 Fuel Oil	33.48
AHP Emergency Generator	Onan	Natural Gas	75 kW
LAS Emergency Generator	Onan	Natural Gas	140 kW
Phase III Emergency Generator	Onan	Natural Gas	12.5 kW
Building 3 Emergency Generator	Penske	Diesel	625 kW
Building 3 Emergency Generator	Penske	Diesel	625 kW
Building 4 Emergency Generator	Detroit Diesel	No. 2 Fuel Oil	1,200 kW
Biopharm, UW-40 Emergency Generator (No. 0471)	Onan	Diesel	750 kW
Repro-Tox Emergency Generator	Onan	Diesel	250 kW
Lab Emergency Generator	Onan	Natural Gas	175 kW
Lab Emergency Generator	Onan	Natural Gas	180 kW
Building 17 Emergency Generator	Onan	Diesel	100 kW
Building 18 Emergency Generator	Onan	Diesel	20 kW
Building 11 Emergency Generator	Marathon	Diesel	510 kW

OPERATING PERMIT CONDITION  
 PERMIT NO. OP-46-0035  
 SMITHKLINE BEECHAM PHARMACEUTICALS  
 (REVISED 10/20/1998)

**CONDITIONS (continued):**

**APPENDIX A**

**Identity and Location of NOx Sources**

Source Description	Manufacturer and Model Number	Fuel Used	Capacity (MMBtu/hr)
Building 20 Emergency Generator	Marathon	Diesel	900 kW
Building 21 Emergency Generator	Marathon	Diesel	510 kW
Building 24 Emergency Generator	Detroit	Diesel	750 kW
Building 38 Emergency Generator	Caterpillar	Diesel	750 kW
Building 38 Emergency Generator	Caterpillar	Diesel	200 kW
Pathological Incinerator Building 3	Sunbeam Equipment Corporation, Model A-35	Natural Gas	4.8 (500 lb/hr)
Pathological Incinerator Building 21	Sunbeam Equipment Corporation, Model A-24	Natural Gas	2.4 (300 lb/hr)
Pathological Incinerator Building 26	International Waste Industries, Model DR 500-S	Natural Gas	4.9 (450 lb/hr)

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