

Air Permit Review

Permit Issue Date: **DRAFT**

Region: Washington Regional Office
County: Pitt
NC Facility ID: 7400021
Inspector's Name: Arni Hopkins
Date of Last Inspection: 08/13/2010
Compliance Code: 3 / Compliance - inspection

Facility Data			Permit Applicability (this application only)
Applicant (Facility's Name): DSM Pharmaceuticals, Inc. Facility Address: DSM Pharmaceuticals, Inc. 5900 Martin Luther King Jr. Hwy. Greenville, NC 27835 SIC: 2833 / Medicinals And Botanicals NAICS: 325412 / Pharmaceutical Preparation Manufacturing Facility Classification: Before: Title V After: Title V Fee Classification: Before: Title V After: Title V			SIP: NSPS: NESHAP: PSD: PSD Avoidance: modify existing limit, 2.2 A. NC Toxics: 112(r): Other:
Contact Data			Application Data
Facility Contact	Authorized Contact	Technical Contact	Application Number: 7400021.11A Date Received: 05/06/2011 Application Type: Modification Application Schedule: TV-Significant Existing Permit Data Existing Permit Number: 05754/T89 Existing Permit Issue Date: 03/07/2011 Existing Permit Expiration Date: 02/28/2016
Wayne Powell Environmental & Utility Operations Mgr (252) 707-2310 5900 Martin Luther King Jr. Hwy. Greenville, NC 27834	Stephen Lijoi Site Director Greenville (252) 707-7635 5900 Martin Luther King Jr. Hwy. Greenville, NC 27834	Wayne Powell Environmental & Utility Operations Mgr (252) 707-2310 5900 Martin Luther King Jr. Hwy. Greenville, NC 27834	
Review Engineer: Kevin Godwin		Comments / Recommendations:	
Review Engineer's Signature: _____		Issue 05754/T90 Permit Issue Date: Permit Expiration Date: 02/28/2016	

I. Introduction and Purpose of Application

- A. DSM operates a pharmaceutical production facility at this Pitt County site. This application for a permit modification was received on May 6, 2011. The application requests an existing PSD avoidance limit for Building 16, Sterile Products Processes (**ID No. B16**) be increased from 0.70 tons VOC to 5.0 tons VOC.
- B. Because this application is for the increase of an existing federally-enforceable limit, it is considered a significant change under Rule 15A NCAC 02Q .0516. The application is being processed under the procedures found in 15A NCAC 02Q .0501(d).

II. Changes to Existing Permit

The following table provides a summary of changes made to existing permit No. 05754T89

Page(s)	Section	Description of Change(s)
Page 1	Permit Cover Page	Amend permit revision numbers and issuance/effective dates.

Page(s)	Section	Description of Change(s)
Page 49	2.2 A.	Changed PSD avoidance limit found in table from 0.7 tons to 5.0 tons per consecutive 12-month period.
Pages 59-67	Section 3	Updated General Conditions to most recent shell version (v3.5).

III. Statement of Compliance

DSM was last inspected on June 13, 15, and 17, 2011 by Mr. Arni Hopkins of the Washington Regional Office (WARO). According to Mr. Hopkins' inspection report dated July 15, 2011, the facility appeared to be in compliance with all applicable regulations and permit conditions at the time of the inspection.

The five-year compliance history is documented in the report as follows:

- “1. On November 7, 2006, DSM was issued an NOV/NRE for failing to meet emission limits from their Solid Waste Incinerator (SWI). On October 27, 2006, the SSCB of the DAQ had notified the Washington Regional Office that they had reviewed and accepted the results of stack tests conducted on the DSM CSWI on June 6 and 7, 2006. The test results for Pb, Cd, and dioxin/furans indicate that the incinerator exceeded the emission standards for these pollutants.

DSM immediately requested that DAQ consider entering into a SOC to allow them to continue to operate the SWI provided they 1) modify/install Control Devices as required to demonstrate compliance and 2) retest to actually demonstrate compliance. The SOC was placed in effect. Modifications were designed/installed and the incinerator was retested on December 3 and 4, 2007. All terms of the SOC had been completed. The results indicated the incinerator was **not in compliance** with the emission limits for CO and Cd. (Additionally, the test charge rate was less than half of the permitted charge rate.) On March 31, 2008, the facility issued a letter stating they did not intend to start/run the SWI in the foreseeable future. On April 7, 2008, an NOV was issued for failing the stack test.

2. On March 12, 2009, DSM was issued an NOV for the late delivery of the CY2008 annual compliance certification.
3. On June 17, 2009, DSM was issued an Administrative order by the USEPA for failing to submit a compliance certification for 2008 prior to March 1, 2009. The State of North Carolina issued DSM an NOV for the same condition (required by their permit) on August 14, 2009.”

IV. Regulatory Review

A. DSM is an existing PSD major stationary source with several PSD avoidance conditions. This permit modification involves a change to the existing PSD avoidance limit found on page 49 (Section 2.2 A.). The condition reads as follows:

1. 15A NCAC 2Q. 0317: AVOIDANCE CONDITIONS

for 15A NCAC 2D .0530: PREVENTION OF SIGNIFICANT DETERIORATION

- a. In order to avoid applicability of this regulation, the above emission sources shall discharge into the atmosphere less than the tabulated tons [0.070 for Building 16] of VOCs per consecutive 12-month period.

Testing [15A NCAC 2Q .0508(f)]

- b. If emissions testing is required, the Permittee shall perform such testing in accordance with General Condition JJ. If the results of this test are above the limit given in Section 2.2 A.1.a., the Permittee shall be deemed in noncompliance with 15A NCAC 2D .0530.

Monitoring/Recordkeeping [15A NCAC 2Q .0508(f)]

- c. Calculations of VOC emissions per month shall be made at the end of each month. VOC emissions shall be determined by using an appropriate calculation method such as the number of batches processed times the "per batch" VOC emission factor. The Permittee shall be deemed in noncompliance with 15A NCAC 2D .0530 if the VOC emissions are not monitored and recorded.
- d. Calculations and the total amount of VOC emissions shall be recorded monthly in a logbook (written or electronic format). The Permittee shall be deemed in noncompliance with 15A NCAC 2D .0530 if the VOC emissions exceed this limit.

Reporting [15A NCAC 2Q .0508(f)]

The Permittee shall submit a summary report of monitoring and recordkeeping activities within 30 days after each calendar year half, due and postmarked on or before January 30 of each calendar year for the preceding six-month period between July and December and July 30 of each calendar year for the preceding six-month period between January and June. The report shall contain the monthly VOC emissions for the previous 17 months. The emissions shall be calculated for each of the six 12-month periods over the previous 17 months.

The applicant was sent an additional information request letter on July 7, 2011 seeking clarification as to why the change is necessary. The questions and responses are as follows:

- a) Provide the basis for the existing 0.70 tons limit and whether this limit was part of any other modification or proposed emission limit. This should include emission factors, process rates and/or the basis for each of these assumptions.
Building 16 was constructed and started-up in the early 1990's. At that time, a small VOC annual emissions limit was included in the operating permit. The small annual emissions limit was based on the projected use of formaldehyde (used for sterilizing) and miscellaneous uses of materials that may contain minor quantities of VOCs.
- b) Describe any changes being proposed at the Sterile Products Facility that might increase the potential emissions or affect the assumptions used to establish the 0.70 ton per year limit.
DSM is proposing to increase the annual VOC emission limit to 5.0 ton per year. This is to allow DSM operational flexibility in an ever changing pharmaceutical market. DSM is seeing that future customers may approach DSM with products that emit VOCs during their production. DSM will not be able to compete with other Manufacturing Contractors if the VOC emission limitation is not increased. There are not any physical modifications of the facility anticipated at this time. This strictly preparing ourselves for the future.
- c) Address the applicability of 40 CFR 51.166(r)(2) which provides in pertinent part "...at such time that a particular source or modification becomes a major stationary source or major modification solely by virtue of a relaxation in any enforceable limitation which was established after August 7, 1980, on the capacity of the source or modification otherwise to emit a pollutant, such as a restriction on hours of operation, then the requirements of paragraphs (j) through (s) of this section shall apply to the source or modification as though construction had not yet commenced on the source or modification."
During the early 1990's, there was a significant number of minor modifications made at the Greenville site. These modifications were tracked as to: 1) Permits Received and Awaiting Startup; 2) Permits Applied For; and, 3) Permits Needed. The Tracking Log Summary for the time period of 9/30/1992-4/7/1994 is attached for your review. As can be seen from the summaries, the total VOC emissions from the three categories never approached the 40 tpy

significant emissions increase and PSD review would not have been triggered during this time period. These are the records currently available.

DAQ agrees that this change will not cause a significant increase for PSD purposes. Thus, the limit will be increased to 5.0 tons.

V. Other Regulatory Considerations

- An application fee of \$867.00 is required and was received with the application.
- The appropriate number of application copies was received by DAQ.
- The application included the Reduction and Recycling Form (A4).
- A Professional Engineer's Seal is not required for this application.
- A zoning consistency determination is required and was received by DAQ (ref. Wayne Harrison, City of Greenville, April 11, 2011).
- Public notice and EPA review are required for this significant modification under 15A NCAC 02Q .0516.
- According to the application the facility is not subject to "Prevention of Accidental Release" under Section 112(r).
- The application was signed by Mr. Stephen Lijoi, VP & Site Director, on April 6, 2011.

VI. Recommendations

This application has been reviewed by DAQ to determine compliance with all procedures and requirements. DAQ has determined that this facility appears to be complying or is expected to achieve compliance as specified in the permit with all applicable requirements.

Issue Permit No. 05747T90.