

DNREC Virtual Public Hearing

Noramco Inc. Application for Natural Minor Construction Permit (Docket #2023-P-A-0018)

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Telephone Audio: DIAL-in Number: 1-646-931-3860

Meeting ID: 881 9242 5025

Access code: 107532

Comments will be accepted using the DNREC Comment form, via email, or by USPS mail as noted on the

hearing event page (de.gov/dnrechearings)



Application Timeline

Action	Date
Application Received	April 13, 2023
Revised Applications Received	July 17, 2023 & August 14, 2023
Legal Notice	August 20, 2023
Public Hearing Request	September 2, 2023
Legal Notice for Public Hearing	October 1, 2023
Community Information Session	October 24, 2023
Public Hearing	November 7, 2023
Public Hearing Public Comment Period Closes	November 22, 2023



Project Summary

- Noramco is a batch pharmaceutical manufacturing facility.
- Noramco is requesting a construction permit to install a new vacuum pump to support a new production line for two new products.
 - The new production line will manufacture intermediates for a medication prescribed to support patients undergoing treatment for cancer, HIV, and anorexia.



Facility-Wide Permit

- Noramco is a major source and operates under a Facility-Wide Title V Permit.
- Facility wide rolling 12-month total emissions are limited to:
 - 20.1 tons per year of volatile organic compounds (VOCs)
 - 10.7 tons per year of combined hazardous air pollutants (HAPs)
 - 9.9 tons per year of individual HAPs
- Noramco is not requesting an increase to Facility Wide emissions as part of this application.



Potential to Emit (PTE)

The uncontrolled emissions for this process were estimated using Emission Master modeling:

Pollutant	D8 PTE (tons/year)	D9 PTE (tons/year)	Total PTE (tons/year)	Major Source Threshold (tons/year)
Volatile Organic Compounds (VOCs)	2.73	2.17	4.9	25
Hazardous Air Pollutants (HAPs)	1.28	1.34	2.6	25



Control Devices

- Emissions from the proposed process are directed to one of two control devices
 - Caustic Scrubber (Destruction Efficiency = 93%)
 - VARA Carbon Adsorber (Destruction Efficiency = 95%)



Controlled Emissions

 The total controlled emissions from each step in the proposed process (D8 and D9) are shown in the table below:

Pollutant	D8 Controlled Emissions (tons/year)	D9 Controlled Emissions (tons/year)	Total Controlled Emissions (tons/year)
Volatile Organic Compounds (VOCs)	0.13	0.36	0.50
Hazardous Air Pollutants (HAPs)	0.08	0.14	0.22



Controlled Emissions

 The total controlled emissions for each pollutant associated with the process are:

Pollutant	Controlled Emissions (ton/yr)
Ethanol	0.015
Ethyl Acetate	0.13
Methanol	0.08
n-Butanol	0.0006
Tetrahydrofuran	0.015
Toluene	0.13
Triethylamine	0.001
Acetone	0.11
Hydrogen Chloride	0.0007
Total VOC (tons)	0.5
Total HAP (tons)	0.22



Facility-Wide Actual Emissions

- Noramco calculates emissions based on a maximum number of batches per year.
- Actual emission are much lower than permitted emissions because there are processes that cannot be run at the same time.
- The Facility-Wide actual emissions for 2021 and 2022 are shown in the table below:

Pollutant	Actual 2021 Emissions (tons)	Actual 2022 Emissions (tons)	
Total Volatile Organic Compounds (VOCs)	1.5	1.48	
Total Hazardous Air Pollutants (HAPs)	0.55	0.88	



AERSCREEN Dispersion Modeling

- Modeling is conducted using AERSCREEN to estimate the maximum downwind concentration (MDC) from a facility.
- The MDC is then compared to Threshold Limit Values (TLVs) exposure limits
 - A safety factor of 100 is applied to account for different ages, health conditions, genders and body types.
 - If the TLV:MDC ratio is greater than 100:1, public health, safety and welfare are presumed to not be adversely impacted by the proposed project.



AERSCREEN Dispersion Modeling

Pollutant	Emission Rate (lb/day)	MDC (μg/m³) (8- hr)	MDC (mg/m³) (8- hr)	TLV (mg/m³)	TLV:MDC
Ethanol	0.5	1.1	0.0011	1884.19	1712900:1
Ethyl Acetate	1.15	2.5	0.0025	1440	576000:1
Methanol	0.7	1.5	0.0015	2.98	1987:1
n-Butanol	0.04	0.09	0.00009	61	677778:1
Tetrahydrofuran	1.87	4.0	0.004	147	36750:1
Toluene	0.9	1.9	0.0019	75	39474:1
Triethylamine	0.01	0.3	0.00003	41.39	1379667:1
Acetone	1.4	0.3	0.003	594	198000:1
Hydrogen Chloride	0.02	0.03	0.00003	262	8733333:1



AERSCREEN Dispersion Modeling

- The TLV:MDC ratios from the addition of the new vacuum pump and process lines exceed DNREC's screening criteria of 100:1
- The emissions are below what would be considered to cause adverse health effects.
- Public health, safety and welfare are presumed to not be adversely impacted.



DAQ Permitting Process

- Review applications for administrative and technical completeness.
- Determine if the source is located in the Coastal Zone and if a Coastal Zone Permit is required.
- Verify proof of local zoning approval.
- Review technical information and confirm emission calculations.
- Legal notice permit application.
- Conduct Air Dispersion Modeling to estimate concentration of air pollutants at the plant's property line to ensure public health, welfare, and safety will not be adversely affected.
- Determine applicable Federal (EPA) and State requirements.
- Draft Technical Memorandum
 - Technical Memorandum is the basis for the emission limits, operating limits, monitoring, test, recordkeeping and reporting requirements included in the permit.



Following the Public Hearing

- If the Secretary approves the permit, then DAQ will issue construction permits that:
 - Meet strict air quality standards under the Federal and Delaware state regulations.
 - Are supported by a detailed technical review and include permit conditions that will protect the environment and public health.
 - Contain permit conditions that may address concerns raised during the public hearing.



Construction to Operation Permitting

- If the construction permits are issued, DAQ will conduct Construction-to-Operation (C to O) Inspections following the completion of construction.
- Following a successful C to O Inspections, the Company will be issued operating permits.



Public Hearing Exhibits

- Application Materials D8/D9 Permit Application; Confidentiality Request
- 2. Request for a Public Hearing Davon Marque Hall
- 3. Hearing Notification Letters Noramco Inc. (Applicant via Certified), Davon Marque Hall
- 4. Public Notice of Application News Journal (8/20/23), Delaware State News (8/20/23), DNREC Website (8/20/23)
- 5. Public Notice of Hearing News Journal (10/1/23), Delaware State news (10/1/23), DNREC Website (10/1/23), Public Meeting Calendar (10/1/23)
- 6. Permit Application Fact Sheet
- 7. DNREC's Presentation





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Thank you for joining us. We will accept comments on this matter through November 22, 2023. Comments may be submitted in writing

via DNREC Comment form - https://dnrec.alpha.delaware.gov/public-hearings/comment-form/via email- - DNRECHearingComments@delaware.gov

or by USPS mail:

Theresa Smith, Hearing Officer

DNREC - Office of the Secretary

89 Kings Highway, Dover, DE 19901

The full verbatim transcript will be posted when it becomes available.

For more information, find the event page for this hearing on the DNREC Public Hearings page dnrec.alpha.delaware.gov/public-hearings/