


STATEMENT OF BASIS FOR A PROPOSED PERMIT TO OPERATE A CLASS II AIR CONTAMINANT SOURCE

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LLCHD Air Quality Program Source Number:	00064		
Proposed Effective Duration of Permit:			
Effective Date:	XX – XX – 2024 <small>MM-DD-YYYY</small>	Expiration Date:	XX – XX – 2029 <small>MM-DD-YYYY</small>

The Lincoln-Lancaster County Health Department (LLCHD) Air Quality Program Hereby Proposes to Issue a Permit to Operate a Class II Source to the Following:

Permit Holder Name:	Haleon US Holdings Inc.
Address:	184 Liberty Corner Road, Suite 200
City, State, ZIP:	Warren, Somerset County, New Jersey 07059

The Proposed Permit is for Operation of the Following Source:

Facility Site Name:	Haleon US Inc.
Facility Address:	10401 Highway 6
City, County, State, ZIP:	Lincoln, Lancaster County, Nebraska, 68517
Facility NAICS:	325412: Pharmaceutical Preparation Manufacturing

In accordance with requirements set forth under Article 2, Section 14 of the Lincoln-Lancaster County Air Pollution Control Programs Regulations and Standards (LLCAPPRS), the LLCHD may not issue a Class II operating permit until the public has been given the opportunity to comment on the draft permit.

Within the 30-day public comment period, any interested person, agency, group, or affected state may request or petition the Director of the LLCHD for a public hearing. All requests for public hearing must be made in writing and must state the nature of the issues to be raised and all arguments and factual grounds supporting their position. If a public hearing is granted by the Director, the hearing will be advertised by public notice at least 30 days prior to its occurrence.

A final determination on this permit will be made following the opportunity of the public to review and comment on the draft permit, and any/all comments received have been addressed.

The conclusion of this document will include a recommendation to either issue or deny the renewal of a Class II operating permit for this source.

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Section 1 – Introduction

Haleon US Inc. (hereinafter referred to as Haleon or the ‘source’), an existing source, has applied to become a Class II ‘minor’ operating facility under the LLCHD (hereinafter also referred to as the ‘Department’). Haleon initially applied for the Class II minor operating permit on August 31, 2018, which met the requirement for a ‘timely submittal’ prior to the operating permit expiration. Haleon has been operating as a Class II ‘synthetic minor’ source until this permitting action.

Changes in source operations and a specific request for consideration of dust control equipment as inherent to the operation of process equipment have resulted in reduced potential emissions Haleon. Further evidence to support source applicability was requested by the Department. Haleon submitted a response on May 12, 2023. The testimony provided was accepted as valid support by the Department, justifying the source dust control equipment as ‘process inherent.’ A revised application was submitted on July 7, 2023, to account for this decision and capture any other source updates.

Construction Permits No. 077B, No. 145, and No. 221 remain applicable for source operations with the incorporation of federally enforceable limits for facility-wide VOC and HAP emissions. Under incorporation of these limits, along with source changes as described in the previous paragraph, this facility now classifies as a Class II, ‘true minor’ source of air pollution and will no longer require a ‘synthetic minor’ permit. The permit incorporates any changes made to the facility during the term of the previous permit, construction permit requirements, and operating permit requirements as applicable.

Article 2, Section 5 of the LLCAPCRS requires that significant sources of air pollutants apply for operating permits. Sources that are required to obtain Class II operating permits are those meeting the criteria set forth under Article 2, Section 5, paragraph (A)(2) of the LLCAPCRS based on their potential to emit.

In accordance with the provisions set forth in LLCAPCRS Article 2, Section 5, paragraph (A)(3), Haleon will operate as a ‘minor’ source, as the maximum potential emissions of regulated pollutants from this source

does not exceed the Class I 'major source' operating permit thresholds set forth in Article 2, Section 5, paragraph (A)(1) of the LLCAPCPRS.

Haleon will be considered an 'area source' of hazardous air pollutants (HAP), as maximum potential emissions of both individual and combined HAPs will be lower than the major source thresholds.

Note: Within this permit, there are references to company names of 'Novartis Consumer Health Inc.' and 'GSK Consumer Health, Inc.' or 'GSK Consumer Health, Inc. DBA Haleon, Inc.' The source is currently registered under the business name of 'Haleon US Holdings Inc.' and is referred to under the trade name of 'Haleon US Inc.' (or simply referred to as Haleon) throughout this permit. All construction permits previously issued to the source using these names remain applicable for this source, unless voided. Any permit issuance to the company name of 'Sandoz Pharmaceuticals Corporation' is no longer active.

Section 2 – Permitting History

2.01 – Construction Permit No. 077 issued August 8, 1995

This permit was issued to Sandoz Pharmaceuticals Corporation for the expansion of production capabilities. The permit allowed for the installation of the following equipment:

- One (1) Lodge Model 2000 Granulator
- One (1) Collette Gral Model 300 Granulator
- One (1) Collette Gral Model 900 Granulator
- Two (2) Glatt Model 300 Fluid Bed Dryers
- Two (2) Gruenberg Tray Dryers
- One (1) Vector Model HC130L Film Coater
- One (1) Vector Model HC130 Film Coater
- Three (3) Torit Cartridge Collector Model DFT2-8 Exhaust Systems

As a condition of the construction permit, Sandoz was required to limit emissions of VOCs from the new equipment to no more than 10 tons per year, and emissions of methyl alcohol (a hazardous air pollutant) were limited to no more than 1,000 pounds per year. Sandoz was required to report emissions associated with the new equipment as part of the annual emission inventory to demonstrate compliance with the VOC and methyl alcohol emission limits.

2.02 – Construction Permit No. 125 issued July 1, 2005

This permit was issued to Novartis for the installation of a Glatt Fluid Bed Dryer. As a condition of the construction permit, Novartis was required to limit emissions of VOCs to no more than 30 tons per year and could not allow the emission of HAPs from the new equipment. In addition, Novartis was also required to control particulate emissions through the use of a Torit Cartridge Filter followed by a HEPA filter. Requirements were established to ensure the proper operation and maintenance of the filter systems, and to require Novartis to report emissions from the new equipment as part of the annual emission inventory to demonstrate compliance with the VOC emission limit. The equipment for which this permit was issued has since been removed, so this permit is not incorporated as an applicable requirement of the proposed operating permit.

2.03 – Construction Permit No. 077A issued June 6, 2006

Subsequent to discovering that Novartis had violated the methyl alcohol emission limit established in Construction Permit No. 077, the permit was revised and re-issued as Construction Permit No. 077A. The revised permit increased the annual emission limit for methyl alcohol from 1,000 pounds per year up to 10,000 pounds per year (5 tons per year). Due to the fact that the increase

in individual HAP exceeded 2.5 tons/year, a 'Best Available Control Technology' (BACT) analysis was submitted as a part of the permit revision application. In addition, the revised permit increased the annual emission limit for VOC from 10 tons per year up to 30 tons per year and revised the VOC emission allocations from those established in Construction Permit No. 077.

2.04 – Initial Class II Synthetic Minor Source Operating Permit and Construction Permit No. 077B issued January 14, 2009

During the drafting of the initial operating permit, Novartis requested that Construction Permit No. 077A be revised to remove the VOC emission limit allocations, and simply apply the 30 ton/year limit to all equipment covered by the permit. The permit was revised and re-issued as Construction Permit No. 077B. Construction Permit No. 077B was issued jointly with the initial operating permit.

The initial operating permit incorporated the revised requirements set forth under Construction Permit No. 077B, as well as the requirements set forth under Construction Permit No. 125. The initial operating permit also incorporated all other local and federal requirements determined to be applicable at the time of issuance.

2.05 – Construction Permit No. 145 issued August 3, 2009

This permit was issued to Novartis for the installation of a pharmaceutical manufacturing line, designated 'Line 79', as well as associated control equipment. This permit established throughput limits and emission limits consistent with the approved application and local regulations. The permit also required the use of dust collectors to control particulate emissions, and established requirements ensuring the proper operation and maintenance of the control equipment.

2.06 – Operating Permit Amendment issued August 10, 2018

This administrative amendment was issued to reflect a change in ownership and name to GSK Consumer Health, Inc. No other changes were made at this time.

2.07 – Construction Permit No. 221 issued March 1, 2023

This permit was issued to GSK Consumer Health, Inc. DBA Haleon, Inc. to supersede and replace the previously issued emergency generator exemption for EU 44-3 to comply with current LLCAPCPRS policy.

2.08 – Proposed Class II Operating Permit Renewal

This document serves as the factual and legal basis for the proposed renewal of the operating permit for Haleon US Inc. The sections that follow provide more information on the source, the nature of emissions from the source, evaluation of the potential to emit, and a discussion of conditions set forth in the draft permit.

Section 3 – Source Characterization

3.01 – Source Description

The primary function of Haleon is the manufacturing and packaging of common pharmaceutical products using material handling, packaging equipment, and three natural gas/#2 fuel oil boilers. Multiple dust collectors – determined as process inherent – are also utilized for both product quality and industrial hygiene purposes.

Haleon has been operating as a Class II 'synthetic minor' source because its maximum potential emissions exceeded Class I (aka, major source) permitting thresholds. Emission calculations contained in the approved application have exhibited that source emissions no longer exceed major source thresholds, and this facility now classifies as a Class II source of air pollution.

Pollutants primarily consist of carbon monoxide (CO), nitrogen oxides (NOx), and sulfur oxides (SOx). Lesser emissions of particulate matter less than or equal to ten micrometers in diameter (PM10) and volatile organic compounds (VOCs) are also associated with this source.

This source is an ‘area source’ of hazardous air pollutants (HAP) because maximum potential emissions of both individual and combined HAPs from combustion equipment, when present at the source, are less than major source thresholds. ‘Major sources’ of HAP are those with a maximum potential to emit individual HAP in excess of 10 tons per year, and total combined HAP in excess of 25 tons per year.

3.02 – Significant Sources of Air Pollution

The operations covered by this permit include the following emissions units:

Emission Unit	SCC Code	Emission Point Description	Emission Segment Description
1-1	1-02-006-02	Kewanee Boiler #1	Natural Gas
1-2	1-02-005-02	Kewanee Boiler #1	#2 Fuel Oil
2-1	1-02-006-02	Kewanee Boiler #2	Natural Gas
2-2	1-02-005-02	Kewanee Boiler #2	#2 Fuel Oil
3-1	1-02-006-02	Kewanee Boiler #3	Natural Gas
3-2	1-02-005-02	Kewanee Boiler #3	#2 Fuel Oil
5-1	5-01-007-01	Wastewater Treatment Plant	Sewage Treatment
8-1	3-01-060-09	SMF Fluid Bed Dryer	Air Dryer
17-1	3-01-060-11	DC A213 (Coating)	Coating Process
40-1	3-01-060-08	Weighing Operations Dust Collector	Exhaust System
43-1	3-01-060-11	DC D441 (Coating)	Coating Process
44-1	2-02-001-02	Fire Pump Engine (235 hp – 175 kW)	Fuel Oil (ULSD)
44-3	2-02-002-53	Natural Gas Emergency Engine (1098 hp – 725 kW)	Natural Gas Combustion
45-1	3-01-060-22	SMF West Granulation, Bin Washing Area	Misc. Fugitives
45-2	3-01-060-22	SMF, Solutions Preparation Area	Misc. Fugitives
45-3	3-01-060-22	SDF, Equipment Cleaning Area	Misc. Fugitives
45-4	3-01-060-22	Packaging Operations	Misc. Fugitives
45-5	3-01-060-22	Equipment Washing Area	Misc. Fugitives
48-1	3-01-060-08	Packaging Dust Collectors	Exhaust System
48-2	3-01-060-08	Packaging Dust Collectors	Exhaust System
50-1	3-85-001-01	Cooling Tower 1	Cooling Tower
51-1	3-85-001-01	Cooling Tower 2	Cooling Tower
52-1	3-85-001-01	Cooling Tower 3	Cooling Tower
53-1	3-85-001-01	Cooling Tower 4	Cooling Tower
54-1	3-85-001-01	Cooling Tower 5	Cooling Tower
55-1	3-01-060-11	Film Coating Dust Collectors	Coating Process
56-1	3-01-060-12	SMF Dust Collectors	Exhaust System
57-1	3-01-060-08	Compression Exhaust Dust Collectors	Exhaust System

Notes:

- Previously permitted Emission Units of 10-1 (Alcohol Storage Area) and 11-1 (Hazardous Waste Storage Area) have established emissions as captured in source processes listed as Emission Units 45-1 through 45-5 and are therefore no longer listed here.

- Previously permitted Emission Units 14-1 (Flavor Storage) and 15-1 (Flavor Dispensing) have been decommissioned from source use and are therefore no longer listed here.
- All previously permitted dust control equipment have been removed as emission units due to process inherent decision and are therefore no longer listed here.

3.03 – Insignificant Activities

For the purposes of this permit, the following are considered insignificant sources of emissions.

Insignificant Activity	Additional Information
Space Heaters	<100,000 Btu/hr - Natural Gas
Fuel Oil Storage	20,000 Gal. Tank – Fuel Oil for Boilers (<10 kPa)
Fuel Oil Storage	300 Gal. Tank – Fuel Oil for fire pump (<10 kPa)
Fuel Oil Storage	500 Gal. Tank –Fuel oil for outdoor lawn care equipment (<10 kPa)
Lab Equipment	Hood/Vent Equipment – for Non-process Activities (minimal exhaust losses)
Chillers	Enclosed Equipment/Boiler Water Treatment (minimal GHG losses)
Fire Suppression	Fire Suppression System (minimal GHG losses)
Water Purification System*	Purified water quality standards as set by United States Pharmacopeia (USP)

*Previously permitted as Emission Unit 46-2 (USP Purified Water System Chlorination).

3.04 – Source Aerial View

Aerial View of Haleon as viewed from the north looking south.



Section 4 – Emission Characterization

4.01 – Emission Calculation Factors and Methods

The procedures for performing emission calculations are provided in the Class II permit application. These procedures will be used to provide the emissions information required for the annual emissions inventory.

4.02 – Maximum Potential Emission Calculations and Totals

4.02.01 – Maximum Potential to Emit (MPTE) – Criteria Pollutants

The following emissions are derived from the approved application for this facility.


Emission Unit	SCC Code	Annual Process Rate	PM ₁₀ (lbs/yr)	PM _{2.5} (lbs/yr)	NO _x (lbs/yr)	SO ₂ (lbs/yr)	VOC (lbs/yr)	CO (lbs/yr)	CO ₂ e (lbs/yr)	LEAD (lbs/yr)	Total HAPs (lbs/yr)
1-1	1-02-006-	149.8 MMcf	1,138	1,138	7,490 ^a	89.9	823.9	12,583	1.81E ⁷	0.07	281.62
1-2	1-02-005-02	1,127 Mgal	2,591	1,746	11,265 ^a	7,998	284.0	5,635	2.76E ⁷	1.42	72.47
2-1	1-02-006-02	149.8 MMcf	1,138	1,138	7,490 ^a	89.9	823.9	12,583	1.81E ⁷	0.07	281.62
2-2	1-02-005-02	1,127 Mgal	2,591	1,746	11,265 ^a	7,998	284.0	5,635	2.76E ⁷	1.42	72.47
3-1	1-02-006-02	149.8 MMcf	1,138	1,138	7,490 ^a	89.9	823.9	12,583	1.81E ⁷	0.07	281.62
3-2	1-02-005-02	1,127 Mgal	2,591	1,746	11,265 ^a	7,998	284.0	5,635	2.76E ⁷	1.42	72.47
5-1	5-01-007-01	5.04E ⁷ gals	-	-	-	-	448.29	-	-	-	-
40-1	3-01-060-08	1.85E ⁷ lbs	46.35	-	-	-	-	-	-	-	-
44-1	2-02-001-02	273,750 gals	664.00	664.00	9,438	620.31	770.31	2,031	353,125	-	0.01
44-3	2-02-002-53	8.19 E ⁷ ft ³	92.54	92.54	10,821	2.8	141.09	17,733	551,777	-	154.27
45-1	3-01-060-22	992.07 lbs	-	-	-	-	625.0	-	-	-	-
45-2	3-01-060-22	3,968 lbs	-	-	-	-	2,500	-	-	-	-
45-3	3-01-060-22	23,151 lbs	-	-	-	-	18,038	-	-	-	-
45-4	3-01-060-22	3,968 lbs	-	-	-	-	2,500	-	-	-	-
45-5	3-01-060-22	992.07 lbs	-	-	-	-	625.0	-	-	-	-
48-1	3-01-060-08	8.46E ⁷ lbs ^c	6,427.25	-	-	-	-	-	-	-	-
48-2	3-01-060-08	8.46E ⁷ lbs ^c	6,427.25	-	-	-	-	-	-	-	-
50-1	3-85-001-01	1.26E ⁹ gals	403.66	-	-	-	-	-	-	-	-
51-1	3-85-001-01	1.26E ⁹ gals	336.38	-	-	-	-	-	-	-	-
52-1	3-85-001-01	1.05E ⁹ gals	336.38	-	-	-	-	-	-	-	-
53-1	3-85-001-01	1.05E ⁹ gals	403.66	-	-	-	-	-	-	-	-
54-1	3-85-001-01	1.26E ⁹ gals	403.66	-	-	-	-	-	-	-	-


Emission Unit	SCC Code	Annual Process Rate	PM ₁₀ (lbs/yr)	PM _{2.5} (lbs/yr)	NO _x (lbs/yr)	SO ₂ (lbs/yr)	VOC (lbs/yr)	CO (lbs/yr)	CO _{2e} (lbs/yr)	LEAD (lbs/yr)	Total HAPs (lbs/yr)
55-1	3-01-060-11	2.41E ⁶ lbs	1,629	-	-	-	-	-	-	-	-
56-1	3-01-060-12	452,191 lbs	72.42	-	-	-	-	-	-	-	-
57-1	3-01-060-08	904,382 lbs	43.45	-	-	-	-	-	-	-	-
8-1	3-01-060-09	2,896,889 lbs	1,448	-	-	-	60,000	-	-	-	10,000
17-1	3-01-060-11	2,414,080 lbs	6,035	-	-	-		-	-	-	
43-1	3-01-060-11	2,414,080 lbs	6,035	-	-	-		-	-	-	
Total Emissions (pounds per year)			32,151	5,995	54,055	24,617		88,119	57,513	83,671,502	
Total Emissions (tons per year)			16.08	3.00	27.03	12.31	44.06	28.76	41,836	0.002	5.50


^a - NO_x emissions from boilers are based on manufacturer-supplied emission factors for low-NO_x burners.

^b - This figure is derived by estimating fuel use based on a maximum of 500 hrs/year of emergency generator use.

^c - This figure is derived from the throughput limit associated with "Line 79" and established per CP No. 145.

 - Cells filled with gray represent emissions that have been omitted from total emissions due to a mutually-exclusive operating scenario. For these emission units, only the worst-case-scenario emissions are presented.

 - Cells filled with orange represent PM₁₀ emission limit as established per CP No. 145.

 - Cells filled with green represent VOC and HAP emission limits as established per CP No. 077B.

4.02.02 – Maximum Potential to Emit (MPTE) – Hazardous Air Pollutants (HAPs)

The MPTE of HAP for this source has primarily been established by the federally enforceable limit established by Construction Permit No. 077B. This construction permit specifically limits material use of methyl alcohol or methanol (CAS # 67-56-1) to 5.0 TPY (10,000 lbs/yr). A small amount of additional HAP emissions are those typically produced as a result of combustion and consist primarily of hexane and formaldehyde and do not emit methyl alcohol. Other fugitive releases from hazardous chemical storage areas (not including methyl alcohol) may also occur.

4.02.03 – MPTE – Permit Threshold Evaluation

The following table summarizes the source’s potential to emit, and compares it to applicable Class I and Class II operating permit thresholds:

Criteria Pollutant	Emissions (tpy)	Class II Permitting Threshold	Meet or Exceed?	Class I Permitting Threshold	Meet or Exceed?
PM ₁₀	16.08	≥ 15 tpy	Yes	≥ 100 tpy	No
PM _{2.5}	3.00	N/A	N/A	N/A	N/A
NO _x	27.03	≥ 40 tpy	No	≥ 100 tpy	No
SO ₂	12.31	≥ 40 tpy	No	≥ 100 tpy	No
VOC	44.06	≥ 40 tpy	Yes	≥ 100 tpy	No
CO	28.76	≥ 50 tpy	No	≥ 100 tpy	No
Lead	0.002	≥ 0.6 tpy	No	≥ 5 tpy	No
CO _{2e}	41,835	N/A	N/A	100,000 tpy	No
Hazardous Air Pollutant	Emissions (tpy)	Class II Permitting Threshold	Meet or Exceed?	Class I Permitting Threshold	Meet or Exceed?
Greatest Single HAP	5.0	≥ 2.5 tpy	Yes	≥ 10.0 tpy	No
Total Combined HAPs	5.502	≥ 10.0 tpy	No	≥ 25.0 tpy	No

4.03 – Limited/Controlled Potential to Emit (LPTE) Emission Calculations and Totals

The owner/operator has not elected to accept any additional emission control requirements, fuel combustion limits, and/or material throughput limits. Therefore, the LPTE for Haleon is the same as the MPTE.

4.04 – Permit Threshold Evaluation

Due to the permit threshold evaluation as reflected in Section 4.02.03, the source exhibits emissions below Class I permitting levels but exceeds Class II operating permit thresholds. As a result, this facility will require a Class II ‘Minor’ operating permit. Because Hazardous Air Pollutant (HAP) emissions are less than Class I permitting thresholds, this facility will continue as an ‘area source’ of HAP emissions.

Section 5 – Applicable Regulations & Requirements

5.01 – Applicable Regulations under the LLCAPCPRS

- (A) The following sections (§) of the LLCAPCPRS listed in Table 1-A are regulations that apply to this source:

Table 1-A: Applicable Regulations of the LLCAPCPRS

Article 1: Administration and Enforcement	
§1	Intent
§2	Unlawful Acts – Permits Required
§3	Violations – Hearings – Orders
§4	Appeal Procedure
§5	Variance
§6	Fees
§7	Compliance – Actions to Enforce – Penalties for Non-Compliance
§8	Procedure for Abatement
§9	Severability
Article 2: Regulations and Standards	
§1	Definitions
§4	Ambient Air Quality Standards
§5	Operating Permits – When Required
§6	Emissions Reporting – When Required
§7	Operating Permits – Application
§8	Operating Permits – Content
§11	Emergency Operating Permits – Defense
§12	Operating Permit Renewal and Expiration
§14	Permits – Public Participation
§15	Permit Modifications – Reopening for Cause
§16	Stack Heights – Good Engineering Practice (GEP)
§17	Construction Permits – When Required
§18	New Source Performance Standards (NSPS)
§20	Particulate Limitations and Standards
§23	National Emission Standards for Hazardous Air Pollutants (NESHAPs)
§27	Hazardous Air Pollutants – Maximum Achievable Control Technology (MACT)
§28	Hazardous Air Pollutants – Source Category Emission Standards
§29	Operating & Construction Permit Emissions Fees
§32	Duty to Prevent Escape of Visible Airborne Dust
§33	Time Schedule for Compliance
§34	Emission Source Testing and Monitoring
§35	Compliance – Exceptions Due to Startup, Shutdown, or Malfunction
§36	Control Regulation Circumvention – When Excepted
§37	Compliance – Responsibility of Owner/Operator Pending Review by Director
§38	Emergency Episodes – Occurrence, Control, and Contingency Plans
Appendices	
I	Emergency Emission Reduction Regulations
II	Hazardous Air Pollutants Sorted by Pollutant Name
III	Hazardous Air Pollutants Sorted by CAS Number

5.02 – Non-Applicable Regulations under the LLCAPCPRS

- (B) The regulations contained within the sections (§) of the LLCAPCPRS listed in Table 1- do not apply to this source at the time of issuance of this permit.

Table 1-B: LLCAPCPRS Regulations not Incorporated in Permit

Article 2: Regulations and Standards	
§2	Major Sources Defined
§9	General Permits
§10	Operating Permits for Temporary Sources
§13	Class I Operating Permit – EPA Review – Affected States Review
§19	Prevention of Significant Deterioration (PSD) of Air Quality
§21	Compliance Assurance Monitoring (CAM)
§22	Incinerator Emission Standards
§24	Sulfur Compound Emission Standards for Existing Sources
§25	Nitrogen Oxide Emissions Standards for Existing Sources
§26	Acid Rain
§3, §30, §31	Reserved

5.03 – Non-Applicable State Regulations

- (C) The State Regulations in Table 1-C Table 1-C below are not requirements of this permit.

Table 1-C: Non-Applicable State Air Quality Regulations

Regulation	Regulation Title
Chapter 4	Prevention of Significant Deterioration of Air Quality

5.04 – Applicable Regulations under the Lincoln Municipal Code

- (D) The local ordinance in Table 1-D is a requirement of this permit:

Table 1-D: Applicable Lincoln Municipal Code (LMC) Chapter(s)

Chapter	Chapter Title
8.06	Air Pollution

5.05 – Applicable Federal Regulations

- (E) The Federal Regulations in Table 1-E below are requirements of this permit.

Table 1-E: Applicable Federal Regulations

40 CFR Part 60: New Source Performance Standards (NSPS)	
<i>Subpart</i>	<i>Subpart Subject</i>
A	General Provisions
Dc	Small Industrial/Commercial/Institutional Steam Generating Units
JJJJ	Stationary Spark Ignition Internal Combustion Engines (SI ICE)
40 CFR Part 61: National Emission Standards for Hazardous Air Pollutants (NESHAPs)	
<i>Subpart</i>	<i>Subpart Subject</i>
A	General Provisions
M	Asbestos
40 CFR Part 63: Source Category NESHAPs	
<i>Subpart</i>	<i>Subpart Subject</i>
A	General Provisions
ZZZZ	NESHAP MACT for Stationary Reciprocating Internal Combustion Engines
40 CFR Part 82: Protection of the Stratospheric Ozone	
<i>Subpart</i>	<i>Subpart Subject</i>
A	Protection and Consumption Controls

B	Servicing Motor Vehicle Air Conditioners
E	Labeling of Products Using Ozone-Depleting Substances
F	Recycling Emissions Reduction
G	Significant New Alternatives Policy Program

5.03 – Non-Applicable Regulations Federal Regulations

(F) The Federal Regulations in Table 1-F below Table 1-F are not requirements of this permit:

Table 1-F: Non-Applicable Federal Regulations

Regulation	Non-Applicable Subparts, Section(s), or Appendix
40 CFR Part 51	Appendix S: Emission Offset Interpretive Ruling
40 CFR Part 52	Subpart A §52.21: Prevention of Significant Deterioration of Air Quality
40 CFR Part 60	All subparts, except those listed as applicable in Table 1-E
40 CFR Part 61	All subparts, except those listed as applicable in Table 1-E
40 CFR Part 63	All subparts, except Subparts B–E and those listed as applicable in Table 1-E
40 CFR Part 64	Entire rule is non-applicable at the time of permit issuance
40 CFR Part 68	Entire rule is non-applicable at the time of permit issuance
40 CFR Part 98	Entire rule is non-applicable at the time of permit issuance

Section 6 – Discussion of Proposed Permit Conditions, Monitoring, Reporting, Notification and Record Keeping Requirements

The following conditions of the proposed permit contain monitoring, reporting, notification, and record keeping requirements. A brief description of these conditions are provided below:

6.01 – General Conditions

Conditions II through XXX are general conditions that are applicable to all Class II sources. There will not be an in-depth discussion of these requirements, except to note the following General Conditions specifically related to monitoring, reporting, notification, and record-keeping:

- VI – Fees
- XI – Annual Emission Reporting
- XII(A) – Timely Applications
- XII(B) – Certification of Truth, Accuracy, and Completeness
- XIII(J) – Permit Copy Maintenance and Retention
- XVI(F) – Notification of Source Modifications
- XXIV(G) – ‘Credible Evidence Rule’
- XXV – Startup, Shutdown, and Malfunction (SSM) Provisions
- XXX(E) – Record Keeping and Retention

6.02 – Specific Conditions

The following are specific conditions of the proposed Class II operating permit:

- XXXI – Authority for Specific Conditions. Authority for this permitting action is established as specified in Condition XXX of the permit. The specific conditions of this permit are in accordance with the requirements of LLCAPCPRS, Article 2, Section 8, paragraphs (M) and (P), as well as Construction Permits No. 077B, No. 145, and No. 221. These conditions apply to all emissions units not otherwise addressed in a Specific Condition on this permit.

- XXXII – Minor Source Requirements. The conditions established under this requirement establish the source as a ‘minor’ source of emissions and provide enforceable conditions requiring the source to maintain actual emissions at levels below ‘major source’ thresholds. These requirements qualify the source for a Class II operating permit. The facility is subject to the monitoring, recordkeeping, and reporting requirements applicable to Class II sources identified in the permit.
- XXXIII – Source Wide Requirements. These conditions apply to the facility and emission unit(s) identified under this condition in the permit. The following conditions have been established pursuant to elections made by the owner/operator in the approved application and the authorities granted in Article 2, Section 8, paragraph (O) of the LLCAPCPRS. These conditions are deemed necessary by the Director to protect public health and/or the environment and are consistent with federally enforceable construction permits held by the owner/operator (if any). All terms and conditions of this permit are enforced by the Administrator and the citizens under the Act, except for those terms and conditions that are specifically designated as not being federally enforceable.

(A) Operating Requirements, Throughput Limits, and/or Work Practice Standards.

The requirements set forth under this condition serve to:

- reiterate the requirement to limit actual emissions to less than the thresholds set forth under Condition XXXII of the proposed permit;
- ensure that the three (3) boilers operate as ‘gas-fired boilers’ in accordance with the definitions set forth under 40 CFR Part 63, Subpart JJJJJ (as long as the boilers are operated in this manner, they will not be subject to the requirements of Subpart JJJJJ – this condition also establishes that, if the source operates the boilers in a manner *inconsistent* with the definition of a ‘gas-fired boiler,’ the source must comply with all applicable requirements of Subpart JJJJJ);
- ensure that the Emission Unit 44-3 (Natural Gas Emergency Engine) is operated in a manner consistent with 40 CFR Part 60, Subpart JJJJ;
- ensure that both engines remain as ‘emergency stationary RICE’ for the purposes of 40 CFR Part 63, Subpart ZZZZ – as defined in §63.6675 of Subpart ZZZZ;
- limit the sulfur content of all fuel oil used in the boilers to no more than 0.5% by weight, which is consistent with the requirements of 40 CFR Part 60, Subpart Dc; and
- recognize that it is the responsibility of the source to implement operating and maintenance procedures according to good air pollution control practices and ensure that source units are operated in such a manner that their contributions to air pollution are minimized.

(B) Emission Limits and Emission Control Requirements.

The requirements set forth under this condition serve to:

- reiterate the emission limit requirements set forth under General Conditions XIX(A) through XIX(D) of the proposed permit – these conditions identify the specific equipment affected by each of the stated emission limits; and
- reference the emission limits established under Construction Permits No. 077B and No. 145.

(C) Monitoring Requirements.

The requirements set forth under this condition serve to:

- establish the requirement to perform periodic visible emission observations to ensure compliance with the opacity limit set forth under Condition XIX(C) of the proposed permit;
- establish the procedures and test methods by which the visible emission surveys should be conducted, as well as the protocols that must be followed upon discovery of excess visible emissions; and
- Implement monitoring requirements established under Construction Permits No. 077B and No. 145 and under applicable Federal Regulations.

(D) Record Keeping Requirements.

The requirements set forth under this condition serve to:

- ensure that the owner/operator keeps adequate records to substantiate emission calculations for the purpose of the required annual emission inventory, as well as demonstrating compliance with the requirement to limit actual emissions to less than the thresholds set forth under Condition XXXII of the proposed permit;
- ensure that the source maintains adequate records to demonstrate compliance with the requirement to perform period visible emission observations;
- reference the record keeping requirements established under applicable Federal Regulations as well as Construction Permits No. 077B and No. 145;
- reiterate record keeping requirements that would go into effect if a change in boiler subcategory should occur under 40 CFR Part 63, Subpart JJJJJ;
- reference the record keeping requirements established under Condition XXX(E) of the proposed permit and establish the requirement to maintain all necessary records to demonstrate compliance with emission control requirements, as well as to demonstrate the permit status as a minor source; and
- ensure records are maintained as required by Condition XI of the proposed permit.

(E) Notification and Reporting Requirements.

The requirements set forth under this condition serve to:

- report emissions to the Department annually, as required by Condition XI of the proposed permit, and establishes what data elements must be included with this report;

- reference the reporting requirements established under Construction Permits No. 077B and No. 145;
- give the Director of the Department authority to require that the owner/operator report material throughput/processing as deemed necessary; and
- reference the notification and reporting requirements established under applicable Federal Regulations.

(F) Requirements of the New Source Performance Standards (NSPS) set forth in Title 40, Part 60 of the Code of Federal Regulations (40 CFR 60).

The requirements set forth under this condition serve to incorporate the applicable requirements of 40 CFR Part 60, Subparts A and Dc as well as 40 CFR Part 60, Subpart JJJ as applicable to the source.

- In regard to the Subpart Dc requirements, is for fuel operating scenarios is based on the date the boiler was constructed, as well as the heat input rating (exceeds 10.0 MMBtu/hr). The Subpart JJJ requirement is applicable only to Emission Unit 44-3 (Natural Gas Emergency Engine).

(G) Requirements of the National Emission Standards for Hazardous Air Pollutants for Source Categories (Source Category NESHAPs) set forth in Title 40, Part 63 of the Code of Federal Regulations (40 CFR 63).

The requirements set forth under this condition serve to incorporate the applicable requirements of 40 CFR Part 63, Subparts A and ZZZZ as applicable to the source. The requirements set forth under this condition specify the terms by which the source engines must operate to remain an 'emergency stationary RICE'.

- Discussion of the conditional exemption under 40 CFR Part 63, Subpart JJJJJ (NESHAP for Industrial, Commercial, and Institutional Boilers at Area Sources) as it pertains to the source boilers is discussed in this section.

(H) Other Requirements.

The requirements set forth under this condition serve to:

- ensure that any controls and monitoring equipment necessary for compliance shall follow proper installation and operation procedures;
- ensure that the Department is notified of any modifications that may result in emission changes at the source; and
- reiterate the incorporation of required testing established under applicable Federal Regulations.

XXXIV – Construction Permit No. 077B Requirements. These conditions apply to the equipment included in Table 34-1 of the proposed permit. All requirements set forth under this condition are derived directly from Construction Permit No. 077B. The basis for these conditions are established in the 'Statement of Basis' for that permit, and as such are settled matters. Refer to Sections 2.01, 2.03,

and 2.04 of this document for more information regarding this operating permit.

- XXXV – Construction Permit No. 145 Requirements. These conditions apply to the equipment included in Table 35-1 of the proposed permit. All requirements set forth under this condition are derived directly from Construction Permit No. 145. The basis for these conditions are established in the ‘Statement of Basis’ for that permit, and as such are settled matters. Refer to Section 2.05 of this document for more information regarding this operating permit.

Section 7 – Summary of Permit Conditions Enforceable by Agency

- (1) LLCHD (Local) – All conditions indicated in this permit with the exception of General Condition (Regulations) I(C).
- (2) EPA (Federal) – All conditions indicated in this permit with the exceptions of General Condition (Regulations) I(F).

Section 8 – Compliance Assurance Monitoring

The Compliance Assurance Monitoring (CAM) requirements set forth under 40 CFR Part 64 only applies to major sources, and Haleon is not a major source for any criteria or hazardous air pollutant. Therefore, the requirements of 40 CFR Part 64 do not apply.

Section 9 – Pollution Prevention Opportunities

The Department encourages the source to continually examine its operations for pollution prevention opportunities. The Department’s Technical Assistance Program can provide resources to aid the facility in exploring available pollution prevention options.

Section 10 – Air Quality Program Recommendation

The Department proposes approval of a Class II Operating Permit for this facility. Enforceable permit conditions have been provided in the draft permit. A final determination on this permit will be made following the opportunity of the public to comment on the draft permit, and any comments received have been addressed.

Section 11 – Public Participation

The following notice is scheduled for publication in the May 13, 2024 edition of the Lincoln Journal Star, which is a newspaper of general circulation in Lancaster County, Nebraska.

This notice, along with the draft permit, statement of basis, and permit application will also be made available on the Lincoln-Lancaster County Health Department (LLCHD) Air Quality Program website at the following URL: <http://lincoln.ne.gov/city/health/environ/Air/PubNot.htm>

PUBLIC NOTICE

LINCOLN-LANCASTER COUNTY HEALTH DEPARTMENT (LLCHD)

- A. In accordance with Article 2, Section 14 of the Lincoln-Lancaster County Air Pollution Control Program Regulations and Standards (LLCAPCPRS), the LLCHD gives notice of the preliminary determination to approve the following permitting action(s) identified below for the source as specified in item ‘B’ following this section. The 30-day public comment period commences May 13, 2024 and ends on June 12, 2024.
1. Proposed issuance of operating permit renewal.

- B. Issuance of the proposed permit allows for operation of the subject emission source within Federal, State and Local requirements. Provided below are the name, address, and the North America Industry Classification System (NAICS) code describing the nature of business at the subject emission source:
1. Owner/Operator Name: Haleon US Holdings Inc.
 2. Source Name: Haleon US Inc.
 3. Source Address: 10401 Highway 6, Lincoln, NE 68517
 4. NAICS Code(s): 325412 – Pharmaceutical Preparation Manufacturing
- C. Potential emissions do not exceed the Class I operating permit thresholds set forth under Article 2, Section 5 of the LLCAPCRS. As a result, this source will be classified as a ‘minor source’ of emissions and issued a Class II operating permit.
- D. The proposed permit will allow for emissions of the following regulated air pollutants in the associated quantities. Any regulated pollutants not listed herein either will not be emitted from the permitted emissions units, or emissions will be negligible. All quantities are in units of tons per year (tpy).
- | | |
|---|---------------|
| Particulate matter <10 micrometers in diameter (PM ₁₀) | 16.08 tpy |
| Particulate matter <2.5 micrometers in diameter (PM _{2.5}) | 3.00 tpy |
| Oxides of Nitrogen (NO _x) | 27.03 tpy |
| Oxides of Sulfur (SO ₂ , SO ₃ , and combinations thereof) | 12.31 tpy |
| Volatile Organic Compounds (VOC) | 44.06 tpy |
| Carbon Monoxide | 28.76 tpy |
| Lead | 0.002 tpy |
| Greatest Individual Hazardous Air Pollutant | 5.00 tpy |
| Total Combined Hazardous Air Pollutants | 5.61 tpy |
| Carbon Dioxide Equivalents | 41,835.75 tpy |
- E. Lancaster County is an ‘attainment/unclassifiable’ area for all pollutants subject to the National Ambient Air Quality Standards (NAAQS), meaning air quality in Lancaster County meets or is cleaner than the national standards. This permitting action is not expected to change that status.
- F. The proposed permit, statement of basis, operating permit application, and a copy of this public notice document are available online at: <http://lincoln.ne.gov>, keyword search “air”. Those materials are also available for inspection during business hours at the office of the LLCHD at 3131 O Street, Lincoln, NE 68510. Telephone inquiries regarding this public notice may be directed to the Air Quality Program at (402) 441-8040. If alternate formats of materials are needed, please notify the Department by calling (402) 441-8040 or (402) 441-6284 for TDD users.
- G. Within the 30-day public comment period, any interested person, agency, or group may submit comments on the proposed permit(s), or request or petition the Director of the LLCHD for a public hearing in accordance with item ‘H’ below. Comments on the proposed permit(s) may be mailed to the attention of the Air Quality Program Supervisor at the address provided in item ‘F’ above, or submitted via e-mail to health@lincoln.ne.gov using the subject line ‘Comment on Air Quality Permit’. Individuals commenting via e-mail are asked to provide their home address and phone number for follow-up correspondence.
- H. Requests for public hearing must be made in writing and must state the nature of the issues to be raised and all arguments and factual grounds supporting their position. If a public hearing is granted by the Director, the hearing will be advertised by public notice at least 30 days prior to its occurrence.

- I. The LLCHD does not discriminate on the basis of race, color, national origin, disability, age, or sex in administration of its programs or activities, and LLCHD does not intimidate or retaliate against any individual or group because of their participation in or opposition to actions protected or prohibited by 40 CFR Part 7, or for the purpose of interfering with any right or privilege guaranteed by 40 CFR Part 7.