

Facility DEC ID: 8263200408

PERMIT
Under the Environmental Conservation Law (ECL)

IDENTIFICATION INFORMATION

Permit Type: Air State Facility
Permit ID: 8-2632-00408/00002
Effective Date: 05/19/2025 Expiration Date: 05/18/2035

Permit Issued To: HU-FRIEDY MFG CO LLC
6789 W HENRIETTA RD
RUSH, NY 14543

Contact: KYLE KOBURI
6789 W HENRIETTA RD
RUSH, NY 14543

Facility: HU-FRIEDY GROUP LLC
6789 W HENRIETTA RD
RUSH, NY 14543

Contact: KYLE KOBURI
6789 W HENRIETTA RD
RUSH, NY 14543

Description:

Initial Air State Facility (ASF) permit for the Hu-Friedy Group, LLC facility located in Rush, New York which produces infection control and sterility assurance indicator products used primarily in the dental industry. The facility currently operates under an Air Facility Registration and is obtaining an ASF permit for the proposed installation and operation of one (1) ethylene oxide (EtO) resistometer (sterilizer) to perform quality assurance testing on samples of finished products.

The proposed EtO resistometer and electric catalytic oxidizer used to control EtO emissions are included as Emission Unit U-00001. The existing flexographic printing and ink mixing operations used to manufacture the indicator products are included under Emission Unit U-00002.

EtO emissions from the resistometer under U-00001 are subject to the requirements of 6 NYCRR Part 212 for Process Emissions Sources and comply with the applicable requirements through operation of the catalytic oxidizer and meeting the ambient guideline concentrations. Multiple monitoring conditions are included in the permit for operation of the catalytic oxidizer and monitoring of EtO emissions and usage.

Flexographic printing operations under U-00002 are subject to the requirements of 6 NYCRR 234 – Graphic Arts Processes. A federally enforceable capping condition under 6 NYCRR 201-7.1 has been included to limit annual VOC emissions below the applicability threshold (25 tpy) for flexographic printing control requirements under 6 NYCRR Part 234.3(a)(1).

The facility operates one (1) permit exempt diesel-fired emergency generator and small permit exempt natural gas-fired rooftop HVAC units. This permit exempt equipment is subject to limited requirements under 6 NYCRR 227-1 for stationary combustion installations. The

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emergency generator must comply with the applicable requirements of 40 CFR 63, Subpart
ZZZZ.

Pursuant to the requirements of Section 7(2) the Climate Leadership and Community Protection Act (CLCPA), the Department has requested and received information regarding the project's consistency with the CLCPA.

By acceptance of this permit, the permittee agrees that the permit is contingent upon strict compliance with the ECL, all applicable regulations, the General Conditions specified and any Special Conditions included as part of this permit.

Permit Administrator: THOMAS P HALEY
 6274 E AVON LIMA RD
 AVON, NY 14414-9519

Authorized Signature: _____ Date: ____ / ____ / ____

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Notification of Other State Permittee Obligations**Item A: Permittee Accepts Legal Responsibility and Agrees to Indemnification**

The permittee expressly agrees to indemnify and hold harmless the Department of Environmental Conservation of the State of New York, its representatives, employees and agents ("DEC") for all claims, suits, actions, and damages, to the extent attributable to the permittee's acts or omissions in connection with the compliance permittee's undertaking of activities in connection with, or operation and maintenance of, the facility or facilities authorized by the permit whether in compliance or not in any compliance with the terms and conditions of the permit. This indemnification does not extend to any claims, suits, actions, or damages to the extent attributable to DEC's own negligent or intentional acts or omissions, or to any claims, suits, or actions naming the DEC and arising under article 78 of the New York Civil Practice Laws and Rules or any citizen suit or civil rights provision under federal or state laws.

Item B: Permittee's Contractors to Comply with Permit

The permittee is responsible for informing its independent contractors, employees, agents and assigns of their responsibility to comply with this permit, including all special conditions while acting as the permittee's agent with respect to the permitted activities, and such persons shall be subject to the same sanctions for violations of the Environmental Conservation Law as those prescribed for the permittee.

Item C: Permittee Responsible for Obtaining Other Required Permits

The permittee is responsible for obtaining any other permits, approvals, lands, easements and rights-of-way that may be required to carry out the activities that are authorized by this permit.

Item D: No Right to Trespass or Interfere with Riparian Rights

This permit does not convey to the permittee any right to trespass upon the lands or interfere with the riparian rights of others in order to perform the permitted work nor does it authorize the impairment of any rights, title, or interest in real or personal property held or vested in a person not a party to the permit.

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DEC GENERAL CONDITIONS

General Provisions

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Facility Level

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| 6 | 5 | Submission of application for permit modification or renewal-REGION 8 HEADQUARTERS |
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DEC GENERAL CONDITIONS****** General Provisions ********GENERAL CONDITIONS - Apply to ALL Authorized Permits.****Condition 1: Facility Inspection by the Department****Applicable State Requirement: ECL 19-0305****Item 1.1:**

The permitted site or facility, including relevant records, is subject to inspection at reasonable hours and intervals by an authorized representative of the Department of Environmental Conservation (the Department) to determine whether the permittee is complying with this permit and the ECL. Such representative may order the work suspended pursuant to ECL 71-0301 and SAPA 401(3).

Item 1.2:

The permittee shall provide a person to accompany the Department's representative during an inspection to the permit area when requested by the Department.

Item 1.3:

A copy of this permit, including all referenced maps, drawings and special conditions, must be available for inspection by the Department at all times at the project site or facility. Failure to produce a copy of the permit upon request by a Department representative is a violation of this permit.

Condition 2: Relationship of this Permit to Other Department Orders and Determinations**Applicable State Requirement: ECL 3-0301 (2) (m)****Item 2.1:**

Unless expressly provided for by the Department, issuance of this permit does not modify, supersede or rescind any order or determination previously issued by the Department or any of the terms, conditions or requirements contained in such order or determination.

Condition 3: Applications for permit renewals, modifications and transfers**Applicable State Requirement: 6 NYCRR 621.11****Item 3.1:**

The permittee must submit a separate written application to the Department for renewal, modification or transfer of this permit. Such application must include any forms or supplemental information the Department requires. Any renewal, modification or transfer granted by the Department must be in writing.

Item 3.2:

The permittee must submit a renewal application at least 180 days before the expiration of permits for Title V and State Facility Permits.

Item 3.3

Permits are transferrable with the approval of the department unless specifically prohibited by the statute, regulation or another permit condition. Applications for permit transfer should be submitted prior to actual transfer of ownership.

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Condition 4: Permit modifications, suspensions or revocations by the Department
Applicable State Requirement: 6 NYCRR 621.13

Item 4.1:

The Department reserves the right to exercise all available authority to modify, suspend, or revoke this permit in accordance with 6NYCRR Part 621. The grounds for modification, suspension or revocation include:

- a) materially false or inaccurate statements in the permit application or supporting papers;
- b) failure by the permittee to comply with any terms or conditions of the permit;
- c) exceeding the scope of the project as described in the permit application;
- d) newly discovered material information or a material change in environmental conditions, relevant technology or applicable law or regulations since the issuance of the existing permit;
- e) noncompliance with previously issued permit conditions, orders of the commissioner, any provisions of the Environmental Conservation Law or regulations of the Department related to the permitted activity.

****** Facility Level ******

Condition 5: Submission of application for permit modification or renewal-REGION 8 HEADQUARTERS
Applicable State Requirement: 6 NYCRR 621.6 (a)

Item 5.1:

Submission of applications for permit modification or renewal are to be submitted to:
 NYSDEC Regional Permit Administrator
 Region 8 Headquarters
 Division of Environmental Permits
 6274 Avon-Lima Road
 Avon, NY 14414-9519
 (585) 226-2466

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Permit Under the Environmental Conservation Law (ECL)

ARTICLE 19: AIR POLLUTION CONTROL - AIR STATE FACILITY PERMIT

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RUSH, NY 14543

Facility: HU-FRIEDY GROUP LLC
6789 W HENRIETTA RD
RUSH, NY 14543

Authorized Activity By Standard Industrial Classification Code:
3843 - DENTAL EQUIPMENT AND SUPPLIES

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- 6 *2 6 NYCRR 201-7.1: Capping Monitoring Condition
- 8 3 6 NYCRR 211.2: Visible Emissions Limited
- 8 4 6 NYCRR 212-2.3 (b): Compliance Demonstration
- 8 5 40CFR 63, Subpart ZZZZ: Applicability

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- 9 6 6 NYCRR 212-1.5 (g): Compliance Demonstration
- 9 7 6 NYCRR 212-2.3 (b): Compliance Demonstration

EU=U-00001,EP=EP001,Proc=001,ES=K0001

- 11 8 6 NYCRR 212-2.3 (b): Compliance Demonstration

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- 13 10 6 NYCRR 212-2.3 (b): Compliance Demonstration

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- 14 11 6 NYCRR 234.5: Compliance Demonstration
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- 21 17 6 NYCRR Subpart 201-5: Emission Unit Definition
- 22 18 6 NYCRR 201-5.2 (c): Renewal deadlines for state facility permits
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- 23 21 6 NYCRR Subpart 201-5: Emission Point Definition By Emission Unit
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NOTE: * preceding the condition number indicates capping.

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FEDERALLY ENFORCEABLE CONDITIONS

FINAL

**** Facility Level ****

NOTIFICATION OF GENERAL PERMITTEE OBLIGATIONS

This section contains terms and conditions which are federally enforceable. Permittees may also have other obligations under regulations of general applicability

Item A: Sealing - 6 NYCRR 200.5

The Commissioner may seal an air contamination source to prevent its operation if compliance with 6 NYCRR Chapter III is not met within the time provided by an order of the Commissioner issued in the case of the violation. Sealing means labeling or tagging a source to notify any person that operation of the source is prohibited, and also includes physical means of preventing the operation of an air contamination source without resulting in destruction of any equipment associated with such source, and includes, but is not limited to, bolting, chaining or wiring shut control panels, apertures or conduits associated with such source.

No person shall operate any air contamination source sealed by the Commissioner in accordance with this section unless a modification has been made which enables such source to comply with all requirements applicable to such modification.

Unless authorized by the Commissioner, no person shall remove or alter any seal affixed to any contamination source in accordance with this section.

Item B: Acceptable Ambient Air Quality - 6 NYCRR 200.6

Notwithstanding the provisions of 6 NYCRR Chapter III, Subchapter A, no person shall allow or permit any air contamination source to emit air contaminants in quantities which alone or in combination with emissions from other air contamination sources would contravene any applicable ambient air quality standard and/or cause air pollution. In such cases where contravention occurs or may occur, the Commissioner shall specify the degree and/or method of emission control required.

Item C: Maintenance of Equipment - 6 NYCRR 200.7

Any person who owns or operates an air contamination source which is equipped with an emission control device shall operate such device and keep it in a satisfactory state of maintenance and repair in accordance with ordinary and necessary practices, standards and procedures, inclusive of manufacturer's specifications,

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required to operate such device effectively.

Item D: Unpermitted Emission Sources - 6 NYCRR 201-1.2

(a) Except as otherwise provided by this Part, construction or operation of a new, modified or existing air contamination source without a registration or permit issued pursuant to this Part is prohibited.

(b) If an existing facility or emission source was subject to the permitting requirements of this Part at the time of construction or modification, and the owner or operator failed to apply for a permit or registration as described in this Part, the owner or operator must apply for a permit or registration in accordance with the provisions of this Part. The facility or emission source is subject to all regulations that were applicable to it at the time of construction or modification and any subsequent requirements applicable to existing emission sources.

Item E: Recycling and Salvage - 6 NYCRR 201-1.7

Where practical, any person who owns or operates an air contamination source shall recycle or salvage air contaminants collected in an air cleaning device according to the requirements of 6 NYCRR.

Item F: Prohibition of Reintroduction of Collected Contaminants to the Air - 6 NYCRR 201-1.8

No person shall unnecessarily remove, handle, or cause to be handled, collected air contaminants from an air cleaning device for recycling, salvage or disposal in a manner that would reintroduce them to the outdoor atmosphere.

Item G: Proof of Eligibility for Sources Defined as Exempt Activities - 6 NYCRR 201-3.2 (a)

The owner and/or operator of an emission source or unit that is eligible to be exempt, may be required to certify that it operates within the specific criteria described in 6 NYCRR Subpart 201-3. The owner or operator of any such emission source must maintain all required records on-site for a period of five years and make them available to representatives of the Department upon request.

Department representatives must be granted access to any facility which contains emission sources or units subject to 6 NYCRR Subpart 201-3, during normal operating hours, for the purpose of determining compliance with this and any other state and federal air pollution control requirements, regulations, or law.

Item H: Proof of Eligibility for Sources Defined as Trivial

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Activities - 6 NYCRR 201-3.3 (a)

The owner and/or operator of an emission source or unit that is listed as being trivial in 6 NYCRR Part 201 may be required to certify that it operates within the specific criteria described in 6 NYCRR Subpart 201-3. The owner or operator of any such emission source must maintain all required records on-site for a period of five years and make them available to representatives of the Department upon request. Department representatives must be granted access to any facility which contains emission sources or units subject to 6 NYCRR Subpart 201-3, during normal operating hours, for the purpose of determining compliance with this and any other state and federal air pollution control requirements, regulations, or law.

Item I: Required Emission Tests - 6 NYCRR 202-1.1

An acceptable report of measured emissions shall be submitted, as may be required by the Commissioner, to ascertain compliance or noncompliance with any air pollution code, rule, or regulation. Failure to submit a report acceptable to the Commissioner within the time stated shall be sufficient reason for the Commissioner to suspend or deny an operating permit. Notification and acceptable procedures are specified in 6 NYCRR Subpart 202-1.

Item J: Open Fires Prohibitions - 6 NYCRR 215.2

Except as allowed by section 215.3 of 6 NYCRR Part 215, no person shall burn, cause, suffer, allow or permit the burning of any materials in an open fire.

Item K: Permit Exclusion - ECL 19-0305

The issuance of this permit by the Department and the receipt thereof by the Applicant does not and shall not be construed as barring, diminishing, adjudicating or in any way affecting any legal, administrative or equitable rights or claims, actions, suits, causes of action or demands whatsoever that the Department may have against the Applicant for violations based on facts and circumstances alleged to have occurred or existed prior to the effective date of this permit, including, but not limited to, any enforcement action authorized pursuant to the provisions of applicable federal law, the Environmental Conservation Law of the State of New York (ECL) and Chapter III of the Official Compilation of the Codes, Rules and Regulations of the State of New York (NYCRR). The issuance of this permit also shall not in any way affect pending or future enforcement actions under the Clean Air Act brought by the United States or any person.

Item L: Federally Enforceable Requirements - 40 CFR 70.6 (b)

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All terms and conditions in this permit required by the Act or any applicable requirement, including any provisions designed to limit a facility's potential to emit, are enforceable by the Administrator and citizens under the Act. The Department has, in this permit, specifically designated any terms and conditions that are not required under the Act or under any of its applicable requirements as being enforceable under only state regulations.

FEDERAL APPLICABLE REQUIREMENTS
The following conditions are federally enforceable.

Condition 1: Facility Permissible Emissions
Effective between the dates of 05/19/2025 and 05/18/2035

Applicable Federal Requirement: 6 NYCRR 201-7.1

Item 1.1:

The sum of emissions from the emission units specified in this permit shall not equal or exceed the following

Potential To Emit (PTE) rate for each regulated contaminant:

CAS No: 0NY998-00-0
Name: VOC

PTE: 10,000 pounds per year

Condition 2: Capping Monitoring Condition
Effective between the dates of 05/19/2025 and 05/18/2035

Applicable Federal Requirement: 6 NYCRR 201-7.1

Item 2.1:

Under the authority of 6 NYCRR Part 201-7, this condition contains an emission cap for the purpose of limiting emissions from the facility, emission unit or process to avoid being subject to the following applicable requirement(s) that the facility, emission unit or process would otherwise be subject to:

6 NYCRR Subpart 201-6
6 NYCRR 234.3 (a)

Item 2.2:

Operation of this facility shall take place in accordance with the approved criteria, emission limits, terms, conditions and standards in this permit.

Item 2.3:

The owner or operator of the permitted facility must maintain all required records on-site for a period of five years and make them available to representatives of the Department upon request. Department representatives must be granted access to any facility regulated by this Subpart,

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during normal operating hours, for the purpose of determining compliance with this and any other state and federal air pollution control requirements, regulations or law.

Item 2.4:

On an annual basis, unless otherwise specified below, beginning one year after the granting of an emissions cap, the responsible official shall provide a certification to the Department that the facility has operated all emission units within the limits imposed by the emission cap. This certification shall include a brief summary of the emissions subject to the cap for that time period and a comparison to the threshold levels that would require compliance with an applicable requirement.

Item 2.5:

The emission of pollutants that exceed the applicability thresholds for an applicable requirement, for which the facility has obtained an emissions cap, constitutes a violation of Part 201 and of the Act.

Item 2.6:

The Compliance Demonstration activity will be performed for the Facility.

Regulated Contaminant(s):

CAS No: 0NY998-00-0 VOC

Item 2.7:

Compliance Demonstration shall include the following monitoring:

Capping: Yes

Monitoring Type: MONITORING OF PROCESS OR CONTROL
DEVICE PARAMETERS AS SURROGATE

Monitoring Description:

To remain exempt from the 6 NYCRR Part 234 VOC RACT control requirements for flexographic printing processes under 6 NYCRR 234.3(a)(1)(a), total facility annual emissions of volatile organic compounds (VOCs) must not exceed 5 tons per year (tpy), on a 12-month rolling basis.

To demonstrate compliance with this limit, total facility VOC emissions must be calculated on a monthly basis and incorporated into a 12-month rolling total. VOC emissions must include emissions from cleaning activities and ink mixing operations. Emissions must be calculated based on the actual monthly ink usage on the presses and monthly cleaning material usage.

Per Item 8.2 above, on an annual basis the facility owner or operator must submit an Annual Capping Report for the prior calendar reporting year on January 30. Records of emissions, material usage, supporting information, and annual certifications must be maintained for a period of at least five years and made available to the Department upon request.

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Parameter Monitored: VOC
 Upper Permit Limit: 5 tons per year
 Monitoring Frequency: MONTHLY
 Averaging Method: 12-MONTH TOTAL, ROLLED MONTHLY
 Reporting Requirements: ANNUALLY (CALENDAR)
 Reports due 30 days after the reporting period.
 The initial report is due 1/30/2026.
 Subsequent reports are due every 12 calendar month(s).

Condition 3: Visible Emissions Limited
Effective between the dates of 05/19/2025 and 05/18/2035

Applicable Federal Requirement:6 NYCRR 211.2

Item 3.1:

Except as permitted by a specific part of this Subchapter and for open fires for which a restricted burning permit has been issued, no person shall cause or allow any air contamination source to emit any material having an opacity equal to or greater than 20 percent (six minute average) except for one continuous six-minute period per hour of not more than 57 percent opacity.

Condition 4: Compliance Demonstration
Effective between the dates of 05/19/2025 and 05/18/2035

Applicable Federal Requirement:6 NYCRR 212-2.3 (b)

Item 4.1:

The Compliance Demonstration activity will be performed for the Facility.

Item 4.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES
 Monitoring Description:

At least 180 days, but not more than eighteen months, prior to the date of permit expiration, the facility owner or operator must submit as part of their next Air State Facility permit renewal application an air dispersion modeling protocol for Department review and approval. Within 60 days of Department approval of the protocol, the facility owner or operator must submit an update to the air dispersion modeling. This should include a review of facility process sources, their emission rates, and applicability of 6 NYCRR Part 212.

Monitoring Frequency: UPON REQUEST OF REGULATORY AGENCY
 Reporting Requirements: ONCE / BATCH OR MONITORING OCCURRENCE

Condition 5: Applicability
Effective between the dates of 05/19/2025 and 05/18/2035

Applicable Federal Requirement:40CFR 63, Subpart ZZZZ

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Item 5.1:

Facilities that have reciprocating internal combustion engines must comply with applicable portions of 40 CFR 63 Subpart ZZZZ.

****** Emission Unit Level ******

Condition 6: Compliance Demonstration
Effective between the dates of 05/19/2025 and 05/18/2035

Applicable Federal Requirement: 6 NYCRR 212-1.5 (g)

Item 6.1:

The Compliance Demonstration activity will be performed for:

Emission Unit: U-00001

Process: 001

Emission Source: K0001

Item 6.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

In accordance with 6 NYCRR 212-1.5(g), the facility owner or operator must properly maintain and operate the catalytic oxidizer (Control K0001) to ensure adequate destruction efficiency is maintained. Regularly scheduled maintenance activities must be performed in accordance with the manufacturer's recommendations.

Records of conducted maintenance activities must be maintained by the facility for a period of at least five years and made available upon request.

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING
DESCRIPTION

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 7: Compliance Demonstration
Effective between the dates of 05/19/2025 and 05/18/2035

Applicable Federal Requirement: 6 NYCRR 212-2.3 (b)

Item 7.1:

The Compliance Demonstration activity will be performed for:

Emission Unit: U-00001

Process: 001

Emission Source: K0001

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Regulated Contaminant(s):

CAS No: 000075-21-8 ETHYLENE OXIDE

Item 7.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: MONITORING OF PROCESS OR CONTROL
DEVICE PARAMETERS AS SURROGATE

Monitoring Description:

To ensure proper operation of the catalytic oxidizer (Control K0001) and on-going compliance with the 99 percent (%) destruction efficiency requirement, while the process is in operation the catalytic oxidizer inlet temperature must not fall below 550 degrees F, on a 1-hour rolling average basis.

As specified under 6 NYCRR 212-1.7(b), to demonstrate compliance with this limit, the facility owner or operator must continuously monitor the inlet temperature to the catalytic oxidizer while the process is in operation. Inlet temperature readings must be recorded at a minimum of once every 15-minutes and incorporated into a 1-hour rolling average. The temperature must be monitored using a continuous monitor that is installed, maintained, and calibrated in accordance with the manufacturer's recommendations.

If the inlet temperature falls below the limit above, the facility owner or operator must take immediate corrective action(s) to restore control equipment to its proper operating temperature. The facility owner or operator must record the reason and duration of any deviations from the limit above and any corrective actions taken.

The temperature monitoring limit is based on manufacturer's recommendations and must be verified during the initial confirmatory testing. If a change in this limit is required based on the initial testing, the facility or operator must submit an application for a minor modification to incorporate the revised temperature limit into the permit.

The facility must keep records of the temperature measurements during testing, 15-minute and 1-hour rolling average temperatures, deviations, corrective actions, and any maintenance or calibration. These records must be kept for a period of at least five years and made available to the Department upon request.

Parameter Monitored: TEMPERATURE

Lower Permit Limit: 550 degrees Fahrenheit

Monitoring Frequency: CONTINUOUS

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Averaging Method: MINIMUM - NOT TO FALL BELOW STATED
VALUE - SEE MONITORING DESCRIPTION

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 8: Compliance Demonstration
Effective between the dates of 05/19/2025 and 05/18/2035

Applicable Federal Requirement: 6 NYCRR 212-2.3 (b)**Item 8.1:**

The Compliance Demonstration activity will be performed for:

Emission Unit: U-00001

Emission Point: EP001

Process: 001

Emission Source: K0001

Regulated Contaminant(s):

CAS No: 000075-21-8 ETHYLENE OXIDE

Item 8.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: INTERMITTENT EMISSION TESTING

Monitoring Description:

Facility process emissions of ethylene oxide have been assigned an Environmental Rating of A by the Department. In accordance with the requirements of 6 NYCRR 212-2.3(b), air contaminants must demonstrate compliance with the applicable guideline concentrations in DEC Program Policy DAR-1. The facility owner or operator demonstrated compliance with the applicable DAR-1 guideline concentrations for these air contaminants in the air dispersion modeling completed at the time of initial permitting.

Consistent with the emission rate used in the modeling, the facility must install and operate a catalytic oxidizer (Control ID K0001) with a minimum ethylene oxide destruction efficiency of 99 percent (%).

To demonstrate compliance with this limit, the facility owner or operator must conduct an initial destruction efficiency test on EP001 within 180 days of the process commencing operation. Testing must be conducted according to EPA Method 320 and the procedures described in 40 CFR 63.365(b)(5)(i). Per 6 NYCRR 202-1, a stack test protocol must be submitted to the Department at least 30 days prior to conducting the test. A stack test report must be submitted to the Department within 60 days of completing the test.

During the testing the facility must continuously monitor the catalyst bed inlet and outlet temperatures. The inlet

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temperature during testing will be used to verify the limit specified elsewhere in this permit. Additionally, the testing must assess whether there is a measurable temperature rise across the catalyst bed (calculated as the average of the differences in each individual measurement of the inlet and outlet temperatures for the duration of the testing).

Subsequent testing must be completed once every ten calendar years. The Department may require additional testing if the facility owner or operator intends to modify the process or control device operation in a manner that could result in increased emissions.

Records of completed stack tests and test protocols must be maintained for a period of at least five years.

Parameter Monitored: DESTRUCTION EFFICIENCY

Lower Permit Limit: 99 percent

Reference Test Method: EPA Method 320

Monitoring Frequency: ONCE EVERY TEN YEARS

Averaging Method: MINIMUM - NOT TO FALL BELOW STATED
VALUE - SEE MONITORING DESCRIPTION

Reporting Requirements: ONCE / BATCH OR MONITORING OCCURRENCE

Condition 9: Compliance Demonstration
Effective between the dates of 05/19/2025 and 05/18/2035

Applicable Federal Requirement: 6 NYCRR 212-2.3 (b)

Item 9.1:

The Compliance Demonstration activity will be performed for:

Emission Unit: U-00001

Emission Point: EP001

Process: 001

Emission Source: S0001

Regulated Contaminant(s):

CAS No: 000075-21-8 ETHYLENE OXIDE

Item 9.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: INTERMITTENT EMISSION TESTING

Monitoring Description:

Facility process emissions of ethylene oxide have been assigned an Environmental Rating of A by the Department. In accordance with the requirements of 6 NYCRR 212-2.3(b), air contaminants must demonstrate compliance with the applicable guideline concentrations in DEC Program Policy DAR-1. The facility owner or operator demonstrated compliance with the applicable DAR-1 guideline concentrations for these air contaminants in the air

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dispersion modeling completed at the time of initial permitting.

Consistent with the emission rate used in the modeling, post-control emissions of ethylene oxide from Emission Point EP001 are limited to 0.333 grams per hour. This emission rate will be met through the installation and operation of a catalytic oxidizer (Control ID K0001).

The facility owner or operator must conduct an initial confirmatory stack test on EP001 within 180 days of the process commencing operation to demonstrate compliance with the above limit. Testing must be conducted according to EPA Method 320 and the procedures described in 40 CFR 63.365(b)(5)(i). Per 6 NYCRR 202-1, a stack test protocol must be submitted to the Department at least 30 days prior to conducting the test. A stack test report must be submitted to the Department within 60 days of completing the test.

Subsequent testing must be completed once every ten calendar years. The Department may require additional testing if the facility owner or operator intends to modify the process or control device operation in a manner that could result in increased emissions.

Records of completed stack tests and supporting documentation must be kept for a period of at least five years.

Parameter Monitored: ETHYLENE OXIDE

Upper Permit Limit: 0.333 grams per hour

Reference Test Method: EPA Method 320

Monitoring Frequency: ONCE EVERY TEN YEARS

Averaging Method: MAXIMUM - NOT TO EXCEED STATED VALUE -
SEE MONITORING DESCRIPTION

Reporting Requirements: ONCE / BATCH OR MONITORING OCCURRENCE

Condition 10: Compliance Demonstration

Effective between the dates of 05/19/2025 and 05/18/2035

Applicable Federal Requirement: 6 NYCRR 212-2.3 (b)

Item 10.1:

The Compliance Demonstration activity will be performed for:

Emission Unit: U-00001

Emission Point: EP001

Process: 001

Emission Source: S0001

Regulated Contaminant(s):

CAS No: 000075-21-8

ETHYLENE OXIDE

Permit ID: 8-2632-00408/00002

Facility DEC ID: 8263200408

Item 10.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: WORK PRACTICE INVOLVING SPECIFIC
OPERATIONS

Monitoring Description:

Facility process emissions of ethylene oxide have been assigned an Environmental Rating of A by the Department. In accordance with the requirements of 6 NYCRR 212-2.3(b), air contaminants must demonstrate compliance with the applicable guideline concentrations in DEC Program Policy DAR-1. The facility owner or operator demonstrated compliance with the applicable DAR-1 guideline concentrations for these air contaminants in the air dispersion modeling completed at the time of initial permitting.

Consistent with the inputs used in the modeling, annual pre-control usage of ethylene oxide is limited to 24.7 pounds per year, on a 365-day rolling average basis. This limit will be met by monitoring the quantity of 100-gram ethylene oxide cylinders used each day and incorporating into a 365-day rolling average.

On an annual basis, the facility owner or operator must submit a summary of EtO usage for the prior calendar year on January 30. This report may be submitted concurrently with the Annual Capping Report for VOCs required elsewhere in this permit. Records of ethylene oxide usage and annual reports must be kept for a period of at least five years.

Work Practice Type: PROCESS MATERIAL THRUPUT

Process Material: ETHYLENE OXIDE

Upper Permit Limit: 24.7 pounds per year

Monitoring Frequency: DAILY

Averaging Method: ANNUAL MAXIMUM ROLLED DAILY

Reporting Requirements: ANNUALLY (CALENDAR)

Reports due 30 days after the reporting period.

The initial report is due 1/30/2026.

Subsequent reports are due every 12 calendar month(s).

Condition 11: Compliance Demonstration

Effective between the dates of 05/19/2025 and 05/18/2035

Applicable Federal Requirement: 6 NYCRR 234.5

Item 11.1:

The Compliance Demonstration activity will be performed for:

Emission Unit: U-00002

Permit ID: 8-2632-00408/00002

Facility DEC ID: 8263200408

Item 11.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

A person shall not sell, specify, or require the application of a coating, ink or adhesive on a substrate if such activity is prohibited by any of the provisions of this Part. The prohibition of this section shall apply to all written or oral contracts under the terms of which a coating, ink or adhesive is to be applied to a substrate.

This prohibition shall not apply to the following:

(1) Ink, coating, or adhesive used in printing processes where control equipment has been installed to demonstrate compliance with this Part; or

(2) Ink, coating, or adhesive used in printing processes that have been granted variances for reasons of technological and economic feasibility per section 234.3(f) of this Part.

A person selling an ink, coating, or adhesive used in a printing process subject to this Part must, upon request, provide the buyer with certification of the VOC content of the coating, ink or adhesive supplied.

Reporting Requirements: AS REQUIRED - SEE MONITORING DESCRIPTION

Condition 12: Compliance Demonstration

Effective between the dates of 05/19/2025 and 05/18/2035

Applicable Federal Requirement:6 NYCRR 234.6

Item 12.1:

The Compliance Demonstration activity will be performed for:

Emission Unit: U-00002

Regulated Contaminant(s):
CAS No: 0NY998-00-0 VOC

Item 12.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

An owner or operator of a facility subject to this Part shall not:

(a) Use open containers to store or dispose of cloth or

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paper impregnated with VOC or solvents that are used for surface preparation, cleanup or the removal of ink, coating or adhesive;

(b) Use open containers to store or dispose of spent or fresh VOC or solvents used for surface preparation, cleanup or the removal of ink, coating or adhesive;

(c) Use open containers to store, dispose or dispense ink, coating or adhesive unless production, sampling, maintenance or inspection procedures require operational access. This provision does not apply to the actual device or equipment designed for the purposes of applying an ink, coating or adhesive to a substrate.

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING DESCRIPTION

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 13: Compliance Demonstration
Effective between the dates of 05/19/2025 and 05/18/2035

Applicable Federal Requirement: 6 NYCRR 234.7

Item 13.1:

The Compliance Demonstration activity will be performed for:

Emission Unit: U-00002

Regulated Contaminant(s):
CAS No: 0NY998-00-0 VOC

Item 13.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

Purchase, use, and production records of ink, coating, adhesive, VOCs, solvent, fountain solution and cleaning material must be maintained in a format acceptable to the Department, and upon request, submitted to the Department. Any other information required to determine compliance with this Part must be provided to the Department in an acceptable format. Records must be maintained at the facility for five years.

The results of an analysis or other procedure used to establish compliance with this Part must be provided to the Department. Department representatives shall be permitted, during reasonable business hours, to obtain ink, coating, adhesive, cleaning material and fountain solution samples to determine compliance with this

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Part.

The owner or operator of a graphic art facility which is not subject to the control requirements of this Part because its annual potential to emit VOC or its total actual VOC emissions, whichever applies is below the applicability criteria, must maintain records in a format acceptable to the Department that verify the facility's annual potential to emit VOC or its total actual VOC emissions. Upon request, these records must be submitted to the Department.

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 14: Compliance Demonstration
Effective between the dates of 05/19/2025 and 05/18/2035

Applicable Federal Requirement: 6 NYCRR 234.8

Item 14.1:

The Compliance Demonstration activity will be performed for the facility:
The Compliance Demonstration applies to:

Emission Unit: U-00002 Emission Point: EP200

Emission Unit: U-00002 Emission Point: EP801

Emission Unit: U-00002 Emission Point: EP802

Item 14.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: MONITORING OF PROCESS OR CONTROL
DEVICE PARAMETERS AS SURROGATE

Monitoring Description:

Emissions from sources subject to the requirements of 6 NYCRR Part 234 shall be limited to 10 percent opacity. Method 9 of Appendix A-4 to 40 CFR Part 60 shall be used to determine opacity.

The facility owner or operator shall conduct a visible emissions observation of all emission points specified by this condition once per day while the process is in operation. The facility owner or operator will investigate, in a timely manner, any instance where there is cause to believe that visible emissions have the potential to exceed the opacity standard specified below.

The facility owner or operator shall investigate the cause, make any necessary corrections, and verify that the

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excess visible emissions problem has been corrected. If visible emissions with the potential to exceed the limit specified are observed for three consecutive operating days from the same emission point, the facility owner or operator will notify the Department of the observations within one business day. The facility owner or operator will also perform an EPA Reference Test Method 9 opacity evaluation analysis of the affected emission point and submit the results to the Department.

Daily records of the visible emissions observations, any follow-up Method 9 observations, investigations, and corrective actions taken are to be maintained on site for a period of at least five years from the date of the record. Such records shall include the date and time of each observation, weather conditions, results of the observation, corrective actions taken, and explanations for days when weather conditions were prohibitive.

All records kept pursuant to this condition must be provided to the Department upon request.

Parameter Monitored: OPACITY

Upper Permit Limit: 10 percent

Reference Test Method: EPA Reference Test Method 9

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING

DESCRIPTION

Averaging Method: 6-MINUTE AVERAGE (METHOD 22)

Reporting Requirements: AS REQUIRED - SEE MONITORING DESCRIPTION

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STATE ONLY ENFORCEABLE CONDITIONS

**** Facility Level ****

NOTIFICATION OF GENERAL PERMITTEE OBLIGATIONS

This section contains terms and conditions which are not federally enforceable. Permittees may also have other obligations under regulations of general applicability

Item A: Emergency Defense - 6 NYCRR 201-1.5

An emergency, as defined in 6 NYCRR subpart 201-2, constitutes an affirmative defense to penalties sought in an enforcement action brought by the department for noncompliance with emissions limitations or permit conditions for all facilities in New York State.

(a) The affirmative defense of emergency shall demonstrate, through properly signed, contemporaneous operating logs, or other relevant evidence that:

(1) an emergency occurred and that the facility owner or operator can identify the cause(s) of the emergency;

(2) the equipment at the facility was being properly operated and maintained;

(3) during the period of the emergency the facility owner or operator took all reasonable steps to minimize the levels of emissions that exceeded the emission standards, or other requirements in the permit; and

(4) the facility owner or operator notified the department within two working days after the event occurred. This notice must contain a description of the emergency, any steps taken to mitigate emissions, and any corrective actions taken.

(b) In any enforcement proceeding, the facility owner or operator seeking to establish the occurrence of an emergency has the burden of proof.

(c) This provision is in addition to any emergency or malfunction provision contained in any applicable requirement.

Item B: Public Access to Recordkeeping for Facilities With State Facility Permits - 6 NYCRR 201-1.10 (a)

Where facility owners and/or operators keep records pursuant to compliance with the requirements of 6 NYCRR Subpart 201-5.4, and/or the emission capping requirements of 6 NYCRR Subpart 201-7, the Department will make such records available to the public upon request in accordance

Permit ID: 8-2632-00408/00002

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with 6 NYCRR Part 616 - Public Access to Records.
Facility owners and/or operators must submit the records
required to comply with the request within sixty working
days of written notification by the Department.

Item C: **General Provisions for State Enforceable Permit Terms and
Condition - 6 NYCRR Part 201-5**

Any person who owns and/or operates stationary sources
shall operate and maintain all emission units and any
required emission control devices in compliance with all
applicable Parts of this Chapter and existing laws, and
shall operate the facility in accordance with all
criteria, emission limits, terms, conditions, and
standards in this permit. Failure of such person to
properly operate and maintain the effectiveness of such
emission units and emission control devices may be
sufficient reason for the Department to revoke or deny a
permit.

The owner or operator of the permitted facility must
maintain all required records on-site for a period of five
years and make them available to representatives of the
Department upon request. Department representatives must
be granted access to any facility regulated by this
Subpart, during normal operating hours, for the purpose of
determining compliance with this and any other state and
federal air pollution control requirements, regulations or
law.

STATE ONLY APPLICABLE REQUIREMENTS

The following conditions are state only enforceable.

Condition 15: Contaminant List

Effective between the dates of 05/19/2025 and 05/18/2035

Applicable State Requirement:ECL 19-0301

Item 15.1:

Emissions of the following contaminants are subject to contaminant specific requirements in
this permit(emission limits, control requirements or compliance monitoring conditions).

CAS No: 000075-21-8
Name: ETHYLENE OXIDE

CAS No: 0NY998-00-0
Name: VOC

Condition 16: Malfunctions and Start-up/Shutdown Activities

Effective between the dates of 05/19/2025 and 05/18/2035

Permit ID: 8-2632-00408/00002

Facility DEC ID: 8263200408

Applicable State Requirement:6 NYCRR 201-1.4**Item 16.1:**

(a) The facility owner or operator shall take all necessary and appropriate actions to prevent the emission of air pollutants that result in contravention of any applicable emission standard during periods of start-up, shutdown, or malfunction.

(b) The facility owner or operator shall compile and maintain records of all equipment maintenance and start-up/shutdown activities when they are expected to result in an exceedance of any applicable emission standard, and shall submit a report of such activities to the department when required by a permit condition or upon request by the department. Such reports shall state whether an exceedance occurred and if it was unavoidable, include the time, frequency and duration of the exceedance, and an estimate of the emission rates of any air contaminants released. Such records shall be maintained for a period of at least five years and made available for review to department representatives upon request. Facility owners or operators subject to continuous monitoring and quarterly reporting requirements need not submit additional reports of exceedances to the department.

(c) In the event that air contaminant emissions exceed any applicable emission standard due to a malfunction, the facility owner or operator shall notify the department as soon as possible during normal working hours, but not later than two working days after becoming aware that the malfunction occurred. In addition, the facility owner or operator shall compile and maintain a record of all malfunctions. Such records shall be maintained at the facility for a period of at least five years and must be made available to the department upon request. When requested by the department, the facility owner or operator shall submit a written report to the department describing the malfunction, the corrective action taken, the air contaminants emitted, and the resulting emission rates and/or opacity.

(d) The department may also require the facility owner or operator to include, in reports described under Subdivisions (b) and (c) of this Section, an estimate of the maximum ground level concentration of each air contaminant emitted and the effect of such emissions.

(e) A violation of any applicable emission standard resulting from start-up, shutdown, or malfunction conditions at a permitted or registered facility may not be subject to an enforcement action by the department and/or penalty if the department determines, in its sole discretion, that such a violation was unavoidable. The actions and recordkeeping and reporting requirements listed above must be adhered to in such circumstances.

Condition 17: Emission Unit Definition**Effective between the dates of 05/19/2025 and 05/18/2035****Applicable State Requirement:6 NYCRR Subpart 201-5****Item 17.1:**

The facility is authorized to perform regulated processes under this permit for:

Emission Unit: U-00001

Emission Unit Description:

Permit ID: 8-2632-00408/00002

Facility DEC ID: 8263200408

Emission Unit U-00001 consists of one (1) ethylene oxide resistometer (sterilizer) unit used to perform quality control and quality assurance operations on sterilizer indicator products manufactured by the facility. Ethylene oxide emissions from the resistometer will be controlled using a catalytic thermal oxidizer.

Building(s): 001

Item 17.2:

The facility is authorized to perform regulated processes under this permit for:

Emission Unit: U-00002

Emission Unit Description:

Emission Unit U-00002 consists of six (6) flexographic printing presses used to print solvent and water - based indicator inks on paper and plastic substrates to manufacture chemical indicators used primarily in the dental industry. Substrates are heat-dried with electric dryers. Two of the presses exhaust to dedicated emission points and the remaining presses are unvented. This emissions unit also includes ink mixing operations and manual cleaning activities for presses, anilox rollers, print plates, and other press equipment by operators.

Building(s): 001

Condition 18: Renewal deadlines for state facility permits
Effective between the dates of 05/19/2025 and 05/18/2035

Applicable State Requirement: 6 NYCRR 201-5.2 (c)

Item 18.1:

The owner or operator of a facility having an issued state facility permit shall submit a complete application at least 180 days, but not more than eighteen months, prior to the date of permit expiration for permit renewal purposes.

Condition 19: Compliance Demonstration
Effective between the dates of 05/19/2025 and 05/18/2035

Applicable State Requirement: 6 NYCRR 201-5.3 (c)

Item 19.1:

The Compliance Demonstration activity will be performed for the Facility.

Item 19.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

Any reports or submissions required by this permit shall be submitted to the Regional Air Pollution Control

Permit ID: 8-2632-00408/00002

Facility DEC ID: 8263200408

Engineer (RAPCE) at the following address:

Division of Air Resources
NYS Dept. of Environmental Conservation
Region 8
6274 East Avon-Lima Rd.
Avon, NY 14414

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 20: Air pollution prohibited
Effective between the dates of 05/19/2025 and 05/18/2035

Applicable State Requirement:6 NYCRR 211.1

Item 20.1:

No person shall cause or allow emissions of air contaminants to the outdoor atmosphere of such quantity, characteristic or duration which are injurious to human, plant or animal life or to property, or which unreasonably interfere with the comfortable enjoyment of life or property. Notwithstanding the existence of specific air quality standards or emission limits, this prohibition applies, but is not limited to, any particulate, fume, gas, mist, odor, smoke, vapor, pollen, toxic or deleterious emission, either alone or in combination with others.

****** Emission Unit Level ******

Condition 21: Emission Point Definition By Emission Unit
Effective between the dates of 05/19/2025 and 05/18/2035

Applicable State Requirement:6 NYCRR Subpart 201-5

Item 21.1:

The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: U-00001

Emission Point: EP001

Height (ft.): 50 Diameter (in.): 6
NYTMN (km.): 4766.356 NYTME (km.): 282.549 Building: 001

Item 21.2:

The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: U-00002

Emission Point: EP200

Height (ft.): 40 Length (in.): 18 Width (in.): 18
NYTMN (km.): 4766.356 NYTME (km.): 282.549 Building: 001

Permit ID: 8-2632-00408/00002

Facility DEC ID: 8263200408

Emission Point: EP801
Height (ft.): 41 Diameter (in.): 12
NYTMN (km.): 4766.356 NYTME (km.): 282.549 Building: 001

Emission Point: EP802
Height (ft.): 41 Diameter (in.): 12
NYTMN (km.): 4766.356 NYTME (km.): 282.549 Building: 001

Emission Point: EPMIX
Height (ft.): 40 Diameter (in.): 12
NYTMN (km.): 4766.356 NYTME (km.): 282.549 Building: 001

Condition 22: Process Definition By Emission Unit
Effective between the dates of 05/19/2025 and 05/18/2035

Applicable State Requirement: 6 NYCRR Subpart 201-5

Item 22.1:

This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: U-00001
Process: 001 Source Classification Code: 3-15-020-01
Process Description:

This process consists of ethylene oxide (EtO) sterilization in a resistometer used for quality assurance of product sterilizer test strips. EtO emissions from the resistometer are controlled using a catalytic oxidizer.

EtO is supplied in sealed 100-gram cartridges and sterilization cycles within the resistometer are performed under vacuum without dichlorofluoromethane injection. Spent cartridges undergo an approximately 6-minute purge with air before being removed from the resistometer. Sterilized test strips are removed from the resistometer following additional air purges. Exhaust during air purge cycles is vented to the catalytic oxidizer.

All sterilization and handling of sterilized test strips occurs within the testing room.

Emission Source/Control: K0001 - Control
Control Type: CATALYTIC OXIDATION

Emission Source/Control: S0001 - Process

Item 22.2:

This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: U-00002
Process: 002 Source Classification Code: 4-05-003-01
Process Description:

Permit ID: 8-2632-00408/00002

Facility DEC ID: 8263200408

This process consists of the flexographic printing of specialized indicator inks on paper and plastic substrates and associated cleaning operations. Printing presses, rollers, plates, or other press equipment are cleaned manually by operators.

Emission Source/Control: PR200 - Process

Emission Source/Control: PR300 - Process

Emission Source/Control: PR500 - Process

Emission Source/Control: PR600 - Process

Emission Source/Control: PR700 - Process

Emission Source/Control: PR800 - Process

Design Capacity: 400 feet per minute

Item 22.3:

This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: U-00002

Process: 003

Source Classification Code: 3-01-020-18

Process Description:

This process includes ink mixing operations consisting of mixing raw materials in 55-gallon drums or 5-gallon pails. Mixing vessels are not purged or cleaned using solvents. Ink mixing operations are conducted within a vented mixing room.

Emission Source/Control: I0001 - Process

Permit ID: 8-2632-00408/00002

Facility DEC ID: 8263200408