



PERMIT
Under the Environmental Conservation Law (ECL)

IDENTIFICATION INFORMATION

Permit Type: Air State Facility
Permit ID: 2-6005-00183/00001
Mod 0 Effective Date: 12/22/1999 Expiration Date: No expiration date.
Mod 1 Effective Date: 12/05/2000 Expiration Date: No expiration date.
Mod 2 Effective Date: 08/06/2003 Expiration Date: No expiration date.
Mod 3 Effective Date: 06/09/2005 Expiration Date: No expiration date.
Mod 4 Effective Date: 04/21/2006 Expiration Date: No expiration date.
Mod 5 Effective Date: 06/30/2006 Expiration Date: No expiration date.
Mod 6 Effective Date: 12/04/2007 Expiration Date: No expiration date.

Permit Issued To: PERRIGO NEW YORK INC
1700 BATHGATE AVE
BRONX, NY 10457

Contact: SOPHIE NAFTALOVICH
PERRIGO NEW YORK INC
1700 BATHGATE AVE
BRONX, NY 10457
(718) 960-0141

Facility: PERRIGO NEW YORK INC-1700 BATHGATE AVE
1700 BATHGATE AVE
BRONX, NY 10457

Contact: SOPHIE NAFTALOVICH
PERRIGO NEW YORK INC
1700 BATHGATE AVE
BRONX, NY 10457
(718) 960-0141

Description:
PERRIGO NEW YORK INC-1700 BATHGATE AVE operates a pharmaceutical manufacturing facility in the Bronx, New York.

Manufacturing of more than hundred pharmaceutical products, mainly creams and ointments, in a batch

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operation process.

With permit Mod 6:

- Emission Unit 070001 - the installation of new equipment comprising the: (1) – Ciclopirox manufacturing train (one new 150-liter vessel and other existing equipment), emission process CIC, and (2) - manufacturing and packaging of various lice treatment products (shampoo, gel, and cream), emission process LIC; are added to this emission unit.
- Emission Unit 070004 – emission process HCP is removed as part of this permit.
- Emission Unit 071001 – emission unit is removed as a part of this permit.
- Emission Unit 0GTEMP – all regulations and standards for the combustion sources, along with a NOx cap of 22.5 tons per year, are removed from this permit with a cancellation of the generator, which was in use only temporary.

The facility VOC emissions are capped at 22.5 tons/year.

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: JOHN F CRYAN
 DIVISION OF ENVIRONMENTAL PERMITS
 ONE HUNTERS POINT PLAZA, 47-40 21ST STREET
 LONG ISLAND CITY, NY 11101-5407

Authorized Signature: _____ Date: ____ / ____ / _____



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 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 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.



LIST OF CONDITIONS

DEC GENERAL CONDITIONS

General Provisions

Facility Inspection by the Department
Relationship of this Permit to Other Department Orders and Determinations
Applications for permit renewals, modifications and transfers
Applications for Permit Renewals and Modifications
Permit modifications, suspensions or revocations by the Department
Applications for Permit Renewals and Modifications
Permit Modifications, Suspensions and Revocations by the Department
Permit Modifications, Suspensions, and Revocations by the Department
Permit Modifications, Suspensions, and Revocations by the Department

Facility Level

Submission of Applications for Permit Modification or Renewal-REGION 2
HEADQUARTERS
Submission of application for permit modification or renewal-REGION 2
HEADQUARTERS



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 6-1: Applications for permit renewals, modifications and transfers
Applicable State Requirement: 6NYCRR 621.11

Item 6-1.1:

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 6-1.2:

The permittee must submit a renewal application at least 180 days before expiration of permits for Title V Facility Permits, or at least 30 days before expiration of permits for State Facility Permits.

Item 6-1.3:

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



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actual transfer of ownership.

Condition 2-1: Applications for Permit Renewals and Modifications
Applicable State Requirement: 6NYCRR 621.13

Item 2-1.1:

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 2-1.2:

The permittee must submit a renewal application at least 180 days before expiration of permits for Title V Facility Permits, or at least 30 days before expiration of permits for State Facility Permits.

Item 2-1.3:

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.

Condition 6-2: Permit modifications, suspensions or revocations by the Department
Applicable State Requirement: 6NYCRR 621.13

Item 6-2.1:

The Department reserves the right 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.

Condition 3: Applications for Permit Renewals and Modifications
Applicable State Requirement: 6NYCRR 621.13(a)

Expired by Mod No: 2

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:



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The permittee must submit a renewal application at least 180 days before expiration of permits for Title V Facility Permits, or at least 30 days before expiration of permits for State Facility Permits.

Condition 2-2: Permit Modifications, Suspensions and Revocations by the Department
Applicable State Requirement: 6NYCRR 621.14

Item 2-2.1:

The Department reserves the right 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.

Condition 4: Permit Modifications, Suspensions, and Revocations by the Department
Applicable State Requirement: 6NYCRR 621.14

Expired by Mod No: 2

Item 4.1:

The Department reserves the right to modify, suspend, or revoke this permit. The grounds for modification, suspension or revocation include:

- a) the scope of the permitted activity is exceeded or a violation of any condition of the permit or provisions of the ECL and pertinent regulations is found;
- b) the permit was obtained by misrepresentation or failure to disclose relevant facts;
- c) new material information is discovered; or
- d) environmental conditions, relevant technology, or applicable law or regulation have materially changed since the permit was issued.

Condition 1-1: Permit Modifications, Suspensions, and Revocations by the Department
Applicable State Requirement: 6NYCRR 621.14

Expired by Mod No: 2

Item 1-1.1:

The Department reserves the right to modify, suspend, or revoke this permit. The grounds for modification, suspension or revocation include:

- a) the scope of the permitted activity described in the application is exceeded or a violation of any condition of the permit or provisions of the ECL and pertinent regulations is found;
- b) the permit was obtained by misrepresentation or failure to disclose relevant facts;
- c) new material information is discovered; or
- d) environmental conditions, relevant technology, or applicable law or regulation have

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materially changed since the permit was issued.

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

**Condition 5: Submission of Applications for Permit Modification or Renewal-REGION 2
HEADQUARTERS
Applicable State Requirement: 6NYCRR 621.5(a)**

Item 5.1:

Submission of applications for permit modification or renewal are to be submitted to:
NYSDEC Regional Permit Administrator
Region 2 Headquarters
Division of Environmental Permits
1 Hunters Point Plaza, 4740 21st Street
Long Island City, NY 11101-5407
(718) 482-4997

**Condition 6-3: Submission of application for permit modification or renewal-REGION 2
HEADQUARTERS
Applicable State Requirement: 6NYCRR 621.6(a)**

Item 6-3.1:

Submission of applications for permit modification or renewal are to be submitted to:
NYSDEC Regional Permit Administrator
Region 2 Headquarters
Division of Environmental Permits
1 Hunters Point Plaza, 4740 21st Street
Long Island City, NY 11101-5407
(718) 482-4997

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Permit Under the Environmental Conservation Law (ECL)

ARTICLE 19: AIR POLLUTION CONTROL - AIR STATE FACILITY PERMIT

IDENTIFICATION INFORMATION

Permit Issued To: PERRIGO NEW YORK INC
1700 BATHGATE AVE
BRONX, NY 10457

Facility: PERRIGO NEW YORK INC-1700 BATHGATE AVE
1700 BATHGATE AVE
BRONX, NY 10457

Authorized Activity By Standard Industrial Classification Code:
2834 - PHARMACEUTICAL PREPARATIONS

Mod 0 Permit Effective Date: 12/22/1999	Permit Expiration Date: No expiration date.
Mod 1 Permit Effective Date: 12/05/2000	Permit Expiration Date: No expiration date.
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Mod 3 Permit Effective Date: 06/09/2005	Permit Expiration Date: No expiration date.
Mod 4 Permit Effective Date: 04/21/2006	Permit Expiration Date: No expiration date.
Mod 5 Permit Effective Date: 06/30/2006	Permit Expiration Date: No expiration date.
Mod 6 Permit Effective Date: 12/04/2007	Permit Expiration Date: No expiration date.



LIST OF CONDITIONS

FEDERALLY ENFORCEABLE CONDITIONS

Facility Level

- 5-1 6NYCRR 201-7.2: Facility Permissible Emissions
- *5-2 6NYCRR 201-7.2: Capping Monitoring Condition

Emission Unit Level

- 5-4 6NYCRR 201-7.2: Process Permissible Emissions

EU=0-70001

- 18 6NYCRR 212.3(a): Compliance Demonstration

EU=0-70002

- 19 6NYCRR 212.3(b): Compliance Demonstration

EU=0-70004

- 21 6NYCRR 212.3(a): Compliance Demonstration

EU=0-71001

- 22 6NYCRR 212.3(a): Compliance Demonstration

STATE ONLY ENFORCEABLE CONDITIONS

Facility Level

- 2-2 ECL 19-0301: Contaminant List
- 2-3 6NYCRR 201-1.4: Unavoidable noncompliance and violations
- 24 6NYCRR 201-5: Emission Unit Definition
- 26 6NYCRR 211.2: Air pollution prohibited

Emission Unit Level

- 29 6NYCRR 201-5: Emission Point Definition By Emission Unit
- 30 6NYCRR 201-5: Process Definition By Emission Unit

NOTE: * preceding the condition number indicates capping.



FEDERALLY ENFORCEABLE CONDITIONS

****** 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 - 6NYCRR Part 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 - 6NYCRR Part 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 - 6NYCRR Part 200.7

Any person who owns or operates an air contamination

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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, required to operate such device effectively.

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

If an existing emission source was subject to the permitting requirements of 6NYCRR Part 201 at the time of construction or modification, and the owner and/or operator failed to apply for a permit for such emission source then the following provisions apply:

(a) The owner and/or operator must apply for a permit for such emission source or register the facility in accordance with the provisions of Part 201.

(b) The emission source or facility is subject to all regulations that were applicable to it at the time of construction or modification and any subsequent requirements applicable to existing sources or facilities.

Item E: Emergency Defense - 6NYCRR Part 201-1.5

An emergency constitutes an affirmative defense to an action brought for noncompliance with emissions limitations or permit conditions for all facilities in New York State.

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

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

(2) The equipment at the permitted facility causing the emergency was at the time being properly operated;

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

(4) The facility owner and/or operator notified the Department within two working days after the event



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occurred. This notice must contain a description of the emergency, any steps taken to mitigate emissions, and corrective actions taken.

(b) In any enforcement proceeding, the facility owner and/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 upset provision contained in any applicable requirement.

Item F: Recycling and Salvage - 6NYCRR Part 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 G: Prohibition of Reintroduction of Collected Contaminants to the Air - 6NYCRR Part 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 H: Proof of Eligibility for Sources Defined as Exempt Activities - 6 NYCRR Part 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 I: Proof of Eligibility for Sources Defined as Trivial Activities - 6 NYCRR Part 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



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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 J: Required Emission Tests - 6 NYCRR Part 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 6NYCRR Part 202-1.

Item K: Visible Emissions Limited - 6 NYCRR Part 211.3

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.

Item L: Open Fires - 6 NYCRR Part 215

No person shall burn, cause, suffer, allow or permit the burning in an open fire of garbage, rubbish for salvage, or rubbish generated by industrial or commercial activities.

Item M: 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



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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 N: Federally Enforceable Requirements - 40 CFR 70.6(b)

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 5-1: Facility Permissible Emissions

Effective between the dates of 06/30/2006 and Permit Expiration Date

Applicable Federal Requirement: 6NYCRR 201-7.2

Item 6-1.1:

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 (From Mod 6) PTE: 45,000 pounds per year
Name: VOC

Condition 5-2: Capping Monitoring Condition

Effective between the dates of 06/30/2006 and Permit Expiration Date

Applicable Federal Requirement: 6NYCRR 201-7.2

Item 5-2.1:

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



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requirement(s) that the facility, emission unit or process would otherwise be subject to:

6NYCRR 201-6

Item 5-2.2:

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

Item 5-2.3:

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, 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 5-2.4:

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 5-2.5:

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 5-2.6:

The Compliance Demonstration activity will be performed for the Facility.

Regulated Contaminant(s):

CAS No: 0NY998-00-0 VOC

Item 5-2.7:

Compliance Demonstration shall include the following monitoring:

Capping: Yes

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

Monitoring Description:

The facility VOC emissions are capped at 22.5 ton per year.

The facility manufactures its products on a campaign basis based upon customer demand. The facility's products can be grouped in the following six product types:

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- glycerin suppository
- hygienic cleansing pads
- creams, ointments, and oil phase materials.

The emission capping method is as follow:
Calculate emissions from one worst-case recipe for each product group. The developed emission factor will be determined as pounds of VOC emissions per the various size batches (e.g., 2.2lb VOC/300-gallon batch). The owner or operator will keep daily records showing the number of batches produced of the different product groups and their batch sizes. Based on the records, the owner or operator will calculate VOC emissions monthly and report it annually.

Parameter Monitored: VOC
Upper Permit Limit: 22.5 tons per year
Monitoring Frequency: DAILY
Averaging Method: ANNUAL MAXIMUM ROLLED MONTHLY
Reporting Requirements: ANNUALLY (CALENDAR)
Reports due 30 days after the reporting period.
The initial report is due 1/30/2007.
Subsequent reports are due every 12 calendar month(s).

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

Condition 5-4: Process Permissible Emissions
Effective between the dates of 06/30/2006 and Permit Expiration Date

Applicable Federal Requirement: 6NYCRR 201-7.2

Item 0-4.1:

The sum of emissions from the regulated process cited shall not exceed the following Potential to Emit (PTE) rates for each regulated contaminant:

Emission Unit: 0-70004 Process: MWH

CAS No: 0NY998-00-0 (From Mod 0)

Name: VOC

PTE(s): 0.15 pounds per hour

232 pounds per year

Emission Unit: 0-71001 Process: WRL



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CAS No: 0NY998-00-0 (From Mod 0)

Name: VOC

PTE(s): 2.77 pounds per hour

22,499 pounds per year

Condition 18: Compliance Demonstration

Effective between the dates of 12/22/1999 and Permit Expiration Date

Applicable Federal Requirement: 6NYCRR 212.3(a)

Item 18.1:

The Compliance Demonstration activity will be performed for:

Emission Unit: 0-70001

Regulated Contaminant(s):

CAS No: 0NY998-00-0 VOC

Item 18.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

VOC EMISSIONS OF ALL NEW BATCH RECIPES
WILL BE CALCULATED AND KEPT ON FILE TO
DEMONSTRATE COMPLIANCE WITH HOURLY
EMISSION LIMITS. SEE ATTACHED AIR GUIDE
- 1 ANALYSIS.

Monitoring Frequency: PER BATCH OF PRODUCT/RAW MATERIAL
CHANGE

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 19: Compliance Demonstration

Effective between the dates of 12/22/1999 and Permit Expiration Date

Applicable Federal Requirement: 6NYCRR 212.3(b)

Item 19.1:

The Compliance Demonstration activity will be performed for:

Emission Unit: 0-70002

Regulated Contaminant(s):

CAS No: 0NY075-00-0 PARTICULATES

Item 19.2:

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Compliance Demonstration shall include the following monitoring:

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

Monitoring Description:

PROCESS WILL NOT OPERATE WITHOUT ITS
CONTROL DEVICE. PRESSURE DROP ACROSS
BAGHOUSE WILL BE MONITORED AND RECORDED
WEEKLY.

Parameter Monitored: PRESSURE CHANGE

Lower Permit Limit: 0.5 inches of water

Upper Permit Limit: 7 inches of water

Monitoring Frequency: WEEKLY

Averaging Method: MAXIMUM - NOT TO BE EXCEEDED AT ANY
TIME (INSTANTANEOUS/DISCRETE OR GRAB)

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 21: Compliance Demonstration
Effective between the dates of 12/22/1999 and Permit Expiration Date

Applicable Federal Requirement: 6NYCRR 212.3(a)

Item 21.1:

The Compliance Demonstration activity will be performed for:

Emission Unit: 0-70004

Regulated Contaminant(s):

CAS No: 0NY998-00-0 VOC

Item 21.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

VOC EMISSIONS OF ALL NEW RECIPES WILL
BE CALCULATED AND KEPT ON FILE TO
DEMONSTRATE COMPLIANCE WITH HOURLY
EMISSION LIMITS. SEE ATTACHED AIR GUIDE
- 1 ANALYSIS.

Monitoring Frequency: PER BATCH OF PRODUCT/RAW MATERIAL
CHANGE

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 22: Compliance Demonstration

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Effective between the dates of 12/22/1999 and Permit Expiration Date

Applicable Federal Requirement: 6NYCRR 212.3(a)

Item 22.1:

The Compliance Demonstration activity will be performed for:

Emission Unit: 0-71001

Regulated Contaminant(s):

CAS No: 0NY998-00-0 VOC

Item 22.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

VOC EMISSIONS OF ALL NEW RECIPES WILL
BE CALCULATED AND KEPT ON FILE TO
DEMONSTRATE COMPLIANCE WITH HOURLY
EMISSION LIMITS. SEE ATTACHED AIR GUIDE
- 1 ANALYSIS.

Monitoring Frequency: PER BATCH OF PRODUCT/RAW MATERIAL
CHANGE

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY



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

Where emission source owners and/or operators keep records pursuant to compliance with the operational flexibility requirements of 6 NYCRR Subpart 201-5.4(b)(1) , and/or the emission capping requirements of 6 NYCRR Subparts 201-7.2(d), 201-7.3(f), 201-7.3(g), 201-7.3(h)(5), 201-7.3(i) and 201-7.3(j), the Department will make such records available to the public upon request in accordance with 6 NYCRR Part 616 - Public Access to Records. Emission source owners and/or operators must submit the records required to comply with the request within sixty working days of written notification by the Department of receipt of the request.

Item B: 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

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law.

STATE ONLY APPLICABLE REQUIREMENTS

The following conditions are state only enforceable.

Condition 2-2: Contaminant List

Effective between the dates of 08/06/2003 and Permit Expiration Date

Applicable State Requirement: ECL 19-0301

Item 2-2.1:

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

CAS No: 0NY075-00-0

Name: PARTICULATES

CAS No: 0NY998-00-0

Name: VOC

Condition 2-3: Unavoidable noncompliance and violations

Effective between the dates of 08/06/2003 and Permit Expiration Date

Applicable State Requirement: 6NYCRR 201-1.4

Item 2-3.1:

At the discretion of the commissioner a violation of any applicable emission standard for necessary scheduled equipment maintenance, start-up/shutdown conditions and malfunctions or upsets may be excused if such violations are unavoidable. The following actions and recordkeeping and reporting requirements must be adhered to in such circumstances.

(a) The facility owner and/or operator shall compile and maintain records of all equipment maintenance or start-up/shutdown activities when they can be expected to result in an exceedance of any applicable emission standard, and shall submit a report of such activities to the commissioner's representative when requested to do so in writing or when so required by a condition of a permit issued for the corresponding air contamination source except where conditions elsewhere in this permit which contain more stringent reporting and notification provisions for an applicable requirement, in which case they supercede those stated here. Such reports shall describe why the violation was unavoidable and shall include the time, frequency and duration of the maintenance and/or start-up/shutdown activities and the identification of air contaminants, and the estimated emission rates. If a facility owner and/or operator is subject to continuous stack monitoring and quarterly reporting requirements, he need not submit reports for equipment maintenance or start-up/shutdown for the facility to the commissioner's representative.

(b) In the event that emissions of air contaminants in excess of any emission standard in 6 NYCRR Chapter III Subchapter A occur due to a malfunction, the facility owner and/or operator shall report such



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malfunction by telephone to the commissioner's representative as soon as possible during normal working hours, but in any event not later than two working days after becoming aware that the malfunction occurred. Within 30 days thereafter, when requested in writing by the commissioner's representative, the facility owner and/or operator shall submit a written report to the commissioner's representative describing the malfunction, the corrective action taken, identification of air contaminants, and an estimate of the emission rates. These reporting requirements are superceded by conditions elsewhere in this permit which contain reporting and notification provisions for applicable requirements more stringent than those above.

(c) The Department may also require the owner and/or operator to include in reports described under (a) and (b) above an estimate of the maximum ground level concentration of each air contaminant emitted and the effect of such emissions depending on the deviation of the malfunction and the air contaminants emitted.

(d) In the event of maintenance, start-up/shutdown or malfunction conditions which result in emissions exceeding any applicable emission standard, the facility owner and/or operator shall take appropriate action to prevent emissions which will result in contravention of any applicable ambient air quality standard. Reasonably available control technology, as determined by the commissioner, shall be applied during any maintenance, start-up/shutdown or malfunction condition subject to this paragraph.

(e) In order to have a violation of a federal regulation (such as a new source performance standard or national emissions standard for hazardous air pollutants) excused, the specific federal regulation must provide for an affirmative defense during start-up, shutdowns, malfunctions or upsets.

Condition 24: Emission Unit Definition

Effective between the dates of 12/22/1999 and Permit Expiration Date

Applicable State Requirement: 6NYCRR 201-5

Item 24.1(From Mod 6):

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

Emission Unit: 0-70001

Emission Unit Description:

Creams, ointments, and oil phase materials manufacturing area. The batch processes are carried out in mixing kettles that exhaust through a common exhaust (room exhausts with prefilter and HEPA filter). Emissions from associated packaging equipment (cream, tube, and liquid filling) are accounted for here also.

With permit Mod6 the installation of new equipment comprising the: (1) - Ciclopirox manufacturing train (one new 150-liter vessel and other existing equipment), and (2) - manufacturing and packaging of various lice treatment products (shampoo, gel, and cream); are added to this emission unit.

Building(s): 1700

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Item 24.2(From Mod 5):

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

Emission Unit: 0-70002

Emission Unit Description:

ONE CHEMICAL WEIGHING ROOM. POWDER RAW MATERIALS ARE WEIGHED IN A MANUAL PROCESS.

Building(s): 1700

Item 24.3(From Mod 5):

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

Emission Unit: 0-70004

Emission Unit Description:

SUPPOSITORIES, CLEASING PAD SOLUTION MANUFACTURING AREA. THE BATCH PROCESSES ARE CARRIED OUT IN 7 MIXING KETTLES. THIS EMISSION UNIT REPRESENTS FUGITIVE EMISSIONS. EMISSIONS FROM ASSOCIATED PACKAGING EQUIPMENT ARE ACCOUNTED FOR HERE ALSO.

Building(s): 1700

Condition 26: Air pollution prohibited

Effective between the dates of 12/22/1999 and Permit Expiration Date

Applicable State Requirement: 6NYCRR 211.2

Item 26.1:

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 29: Emission Point Definition By Emission Unit

Effective between the dates of 12/22/1999 and Permit Expiration Date

Applicable State Requirement: 6NYCRR 201-5

Item 29.1(From Mod 6):



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

Emission Unit: 0-70001

Emission Point: 70011

Height (ft.): 26 Length (in.): 24 Width (in.): 24
NYTMN (km.): 4521.8 NYTME (km.): 592.8 Building: 1700

Emission Point: 70021

Height (ft.): 26 Length (in.): 24 Width (in.): 24
NYTMN (km.): 4521.8 NYTME (km.): 592.8 Building: 1700

Emission Point: 70001

Height (ft.): 26 Diameter (in.): 26
NYTMN (km.): 4521.923 NYTME (km.): 592.733 Building: 1700

Item 29.2(From Mod 0):

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

Emission Unit: 0-70002

Emission Point: 70002

Height (ft.): 32 Length (in.): 12 Width (in.): 12
NYTMN (km.): 4521.923 NYTME (km.): 592.733 Building: 1700

Item 29.3(From Mod 0):

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

Emission Unit: 0-70003

Emission Point: 70003

Height (ft.): 26 Diameter (in.): 24
NYTMN (km.): 4521.923 NYTME (km.): 592.733 Building: 1700

Item 29.4(From Mod 0):

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

Emission Unit: 0-71001

Emission Point: 71001

Height (ft.): 38 Length (in.): 11 Width (in.): 9
NYTMN (km.): 4521.923 NYTME (km.): 592.733 Building: 1701

Condition 30: Process Definition By Emission Unit
Effective between the dates of 12/22/1999 and Permit Expiration Date

Applicable State Requirement: 6NYCRR 201-5

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Item 30.1(From Mod 6):

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

Emission Unit: 0-70001

Process: CIC

Source Classification Code: 3-01-060-99

Process Description:

Manufacturing and packaging of Ciclopirox products (topical antifungal cream). Maximum Batch Rate is 20 300-kg batches per year.

Emission Source/Control: 00CIC - Process

Design Capacity: 20 batches per year

Item 30.2(From Mod 6):

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

Emission Unit: 0-70001

Process: LIC

Source Classification Code: 3-01-060-99

Process Description:

Manufacturing and packaging of various lice treatment products (shampoo, gell, and cream). Maximum Batch Rate is 102 batches per year.

Emission Source/Control: 00LIC - Process

Design Capacity: 102 batches per year

Item 30.3(From Mod 5):

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

Emission Unit: 0-70001

Process: COO

Source Classification Code: 3-01-060-99

Process Description:

CREAMS, OINTMENTS, AND OIL PASTE MATERIALS MANUFACTURING AREA. THE BATCH PROCESSES ARE CARRIED OUT IN 35 MIXING KETTLES THAT EXHAUST THROUGH A COMMON EXHAUST. EMISSIONS FROM PACKAGING EQUIPMENT (CREAM, TUBE, AND LIQUID FILLING) ARE ACCOUNTED FOR HERE.

Emission Source/Control: 00008 - Process

Emission Source/Control: 00011 - Process

Emission Source/Control: 00013 - Process



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- Emission Source/Control: 00021 - Process
- Emission Source/Control: 00275 - Process
- Emission Source/Control: 00277 - Process
- Emission Source/Control: 00278 - Process
- Emission Source/Control: 00285 - Process
- Emission Source/Control: 00287 - Process
- Emission Source/Control: 00288 - Process
- Emission Source/Control: 00289 - Process
- Emission Source/Control: 00313 - Process
- Emission Source/Control: 00421 - Process
- Emission Source/Control: 00425 - Process
- Emission Source/Control: 00496 - Process
- Emission Source/Control: 00504 - Process
- Emission Source/Control: 0PKG1 - Process
- Emission Source/Control: 0PKG2 - Process
- Emission Source/Control: 0PKG3 - Process

Item 30.4(From Mod 5):

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

Emission Unit: 0-70002

Process: WGR

Source Classification Code: 3-01-060-99

Process Description:

1 CHEMICAL WEIGHING ROOM. RAW MATERIALS (POWDERS AND LIQUIDS) ARE WEIGHED IN A MANUAL PROCESS IN THIS AREA. ONE ELEPHANT TRUNK PICKUP CONNECTED TO THE EXHAUST PER ROOM.

Emission Source/Control: C7002 - Control

Control Type: FABRIC FILTER

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Emission Source/Control: 00104 - Process

Emission Source/Control: 00105 - Process

Emission Source/Control: 00106 - Process

Item 30.5(From Mod 5):

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

Emission Unit: 0-70004

Process: SUP

Source Classification Code: 3-01-060-99

Process Description:

SUPPOSITORY MANUFACTURING AREA. THE BATCH
PROCESSES ARE CARRIED OUT IN 5 MIXING
KETTLES.

Emission Source/Control: 00140 - Process

Design Capacity: 100 gallons

Emission Source/Control: 00141 - Process

Design Capacity: 50 gallons

Emission Source/Control: 00537 - Process

Design Capacity: 150 gallons

Emission Source/Control: 00538 - Process

Design Capacity: 300 gallons

Emission Source/Control: CPL10 - Process

Design Capacity: 300 gallons