



State of Ohio Environmental Protection Agency

**RE: FINAL PERMIT TO INSTALL  
WARREN COUNTY**

**CERTIFIED MAIL**

Street Address:

122 S. Front Street

Lazarus Gov. Center TELE: (614) 644-3020 FAX: (614) 644-2329

Mailing Address:

Lazarus Gov. Center  
P.O. Box 1049

**Application No: 14-05511**

**DATE: 4/8/2004**

Pharmacia Hepar Inc  
Scott Triick  
160 Industrial Drive  
Franklin, OH 45005-0000

Enclosed please find an Ohio EPA Permit to Install which will allow you to install the described source(s) in a manner indicated in the permit. Because this permit contains several conditions and restrictions, I urge you to read it carefully.

The Ohio EPA is urging companies to investigate pollution prevention and energy conservation. Not only will this reduce pollution and energy consumption, but it can also save you money. If you would like to learn ways you can save money while protecting the environment, please contact our Office of Pollution Prevention at (614) 644-3469.

You are hereby notified that this action by the Director is final and may be appealed to the Ohio Environmental Review Appeals Commission pursuant to Chapter 3745.04 of the Ohio Revised Code. The appeal must be in writing and set forth the action complained of and the grounds upon which the appeal is based. It must be filed within thirty (30) days after the notice of the Directors action. A copy of the appeal must be served on the Director of the Ohio Environmental Protection Agency within three (3) days of filing with the Commission. An appeal may be filed with the Environmental Review Appeals Commission at the following address:

Environmental Review Appeals Commission  
309 South Fourth Street, Room 222  
Columbus, Ohio 43215

Sincerely,

Michael W. Ahern, Supervisor  
Field Operations and Permit Section  
Division of Air Pollution Control

cc: USEPA

HCDES



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**Permit To Install  
Terms and Conditions**

**Issue Date: 4/8/2004  
Effective Date: 4/8/2004**

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**FINAL PERMIT TO INSTALL 14-05511**

Application Number: 14-05511  
APS Premise Number: 1483040192  
Permit Fee: **\$3000**  
Name of Facility: Pharmacia Hepar Inc  
Person to Contact: Scott Triick  
Address: 160 Industrial Drive  
Franklin, OH 45005-0000

Location of proposed air contaminant source(s) [emissions unit(s)]:

**160 Industrial Drive  
Franklin, Ohio**

Description of proposed emissions unit(s):

**Sodium Heparin production process.**

The above named entity is hereby granted a Permit to Install for the above described emissions unit(s) pursuant to Chapter 3745-31 of the Ohio Administrative Code. Issuance of this permit does not constitute expressed or implied approval or agreement that, if constructed or modified in accordance with the plans included in the application, the above described emissions unit(s) of environmental pollutants will operate in compliance with applicable State and Federal laws and regulations, and does not constitute expressed or implied assurance that if constructed or modified in accordance with those plans and specifications, the above described emissions unit(s) of pollutants will be granted the necessary permits to operate (air) or NPDES permits as applicable.

This permit is granted subject to the conditions attached hereto.

Ohio Environmental Protection Agency

Director

## Part I - GENERAL TERMS AND CONDITIONS

### A. Permit to Install General Terms and Conditions

#### 1. Compliance Requirements

The emissions unit(s) identified in this Permit to Install shall remain in full compliance with all applicable State laws and regulations and the terms and conditions of this permit.

#### 2. Reporting Requirements

The permittee shall submit required reports in the following manner:

- a. Reports of any required monitoring and/or recordkeeping information shall be submitted to the appropriate Ohio EPA District Office or local air agency.
- b. Except as otherwise may be provided in the terms and conditions for a specific emissions unit, quarterly written reports of (a) any deviations (excursions) from emission limitations, operational restrictions, and control device operating parameter limitations that have been detected by the testing, monitoring, and recordkeeping requirements specified in this permit, (b) the probable cause of such deviations, and (c) any corrective actions or preventive measures which have been or will be taken, shall be submitted to the appropriate Ohio EPA District Office or local air agency. If no deviations occurred during a calendar quarter, the permittee shall submit a quarterly report, which states that no deviations occurred during that quarter. The reports shall be submitted quarterly, i.e., by January 31, April 30, July 31, and October 31 of each year and shall cover the previous calendar quarters. (These quarterly reports shall exclude deviations resulting from malfunctions reported in accordance with OAC rule 3745-15-06.)

#### 3. Records Retention Requirements

Each record of any monitoring data, testing data, and support information required pursuant to this permit shall be retained for a period of five years from the date the record was created. Support information shall include, but not be limited to, all calibration and maintenance records and all original strip-chart recordings for continuous monitoring instrumentation, and copies of all reports required by this permit. Such records may be maintained in computerized form.

#### 4. Inspections and Information Requests

The Director of the Ohio EPA, or an authorized representative of the Director, may, subject to the safety requirements of the permittee and without undue delay, enter upon the premises of this source at any reasonable time for purposes of making inspections, conducting tests, examining records or reports pertaining to any emission of air contaminants, and determining compliance with any applicable State air pollution laws and regulations and the terms and conditions of this permit. The permittee shall furnish to the Director of the Ohio EPA, or an authorized

representative of the Director, upon receipt of a written request and within a reasonable time, any information that may be requested to determine whether cause exists for modifying, reopening or revoking this permit or to determine compliance with this permit. Upon verbal or written request, the permittee shall also furnish to the Director of the Ohio EPA, or an authorized representative of the Director, copies of records required to be kept by this permit.

**5. Scheduled Maintenance/Malfunction Reporting**

Any scheduled maintenance of air pollution control equipment shall be performed in accordance with paragraph (A) of OAC rule 3745-15-06. The malfunction of any emissions units or any associated air pollution control system(s) shall be reported to the appropriate Ohio EPA District Office or local air agency in accordance with paragraph (B) of OAC rule 3745-15-06. Except as provided in that rule, any scheduled maintenance or malfunction necessitating the shutdown or bypassing of any air pollution control system(s) shall be accompanied by the shutdown of the emissions unit(s) that is (are) served by such control system(s).

**6. Permit Transfers**

Any transferee of this permit shall assume the responsibilities of the prior permit holder. The appropriate Ohio EPA District Office or local air agency must be notified in writing of any transfer of this permit.

**7. Air Pollution Nuisance**

The air contaminants emitted by the emissions units covered by this permit shall not cause a public nuisance, in violation of OAC rule 3745-15-07.

**8. Termination of Permit to Install**

This Permit to Install shall terminate within eighteen months of the effective date of the Permit to Install if the owner or operator has not undertaken a continuing program of installation or modification or has not entered into a binding contractual obligation to undertake and complete within a reasonable time a continuing program of installation or modification. This deadline may be extended by up to 12 months if application is made to the Director within a reasonable time before the termination date and the party shows good cause for any such extension.

**9. Construction of New Sources(s)**

The proposed emissions unit(s) shall be constructed in strict accordance with the plans and application submitted for this permit to the Director of the Ohio Environmental Protection Agency. There may be no deviation from the approved plans without the express, written approval of the Agency. Any deviations from the approved plans or the above conditions may lead to such sanctions

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**PTI Application: 14-05511**  
**Issued: 4/8/2004**

**Facility ID: 1483040192**

and penalties as provided under Ohio law. Approval of these plans does not constitute an assurance that the proposed facilities will operate in compliance with all Ohio laws and regulations. Additional facilities shall be installed upon orders of the Ohio Environmental Protection Agency if the proposed sources cannot meet the requirements of this permit or cannot meet applicable standards.

If the construction of the proposed emissions unit(s) has already begun or has been completed prior to the date the Director of the Environmental Protection Agency approves the permit application and plans, the approval does not constitute expressed or implied assurance that the proposed facility has been constructed in accordance with the approved plans. The action of beginning and/or completing construction prior to obtaining the Director's approval constitutes a violation of OAC rule 3745-31-02. Furthermore, issuance of the Permit to Install does not constitute an assurance that the proposed source will operate in compliance with all Ohio laws and regulations. Approval of the plans in any case is not to be construed as an approval of the facility as constructed and/or completed. Moreover, issuance of the Permit to Install is not to be construed as a waiver of any rights that the Ohio Environmental Protection Agency (or other persons) may have against the applicant for starting construction prior to the effective date of the permit. Additional facilities shall be installed upon orders of the Ohio Environmental Protection Agency if the proposed facilities cannot meet the requirements of this permit or cannot meet applicable standards.

**10. Public Disclosure**

The facility is hereby notified that this permit, and all agency records concerning the operation of this permitted source, are subject to public disclosure in accordance with OAC rule 3745-49-03.

**11. Applicability**

This Permit To Install is applicable only to the emissions unit(s) identified in the Permit To Install. Separate Permit To Install for the installation or modification of any other emissions unit(s) are required for any emissions unit for which a Permit To Install is required.

**12. Best Available Technology**

As specified in OAC Rule 3745-31-05, all new sources must employ Best Available Technology (BAT). Compliance with the terms and conditions of this permit will fulfill this requirement.

**13. Source Operation and Operating Permit Requirements After Completion of Construction**

This facility is permitted to operate each source described by this Permit to Install for a period of up to one year from the date the source commenced operation. This permission to operate is granted only if the facility complies with all requirements contained in this permit and all applicable air pollution laws, regulations, and policies. Pursuant to OAC Chapter 3745-35, the permittee shall submit a complete operating permit application within ninety (90) days after commencing operation of the emissions unit(s) covered by this permit.

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**14. Construction Compliance Certification**

The applicant shall provide Ohio EPA with a written certification (see enclosed form) that the facility has been constructed in accordance with the Permit to Install application and the terms and conditions of the Permit to Install. The certification shall be provided to Ohio EPA upon completion of construction but prior to startup of the source.

**15. Fees**

The permittee shall pay fees to the Director of the Ohio EPA in accordance with ORC section 3745.11 and OAC Chapter 3745-78. The permittee shall pay all applicable Permit to Install fees within 30 days after the issuance of this Permit to Install.

**B. Permit to Install Summary of Allowable Emissions**

The following information summarizes the total allowable emissions, by pollutant, based on the individual allowable emissions of each air contaminant source identified in this permit.

SUMMARY (for informational purposes only)  
TOTAL PERMIT TO INSTALL ALLOWABLE EMISSIONS

<u>Pollutant</u>	<u>Tons Per Year</u>
OC	37.7

**PART II - SPECIAL TERMS AND CONDITIONS FOR SPECIFIC EMISSIONS UNIT(S)**

**A. Applicable Emissions Limitations and/or Control Requirements**

1. The specific operations(s), property, and/or equipment which constitute this emissions unit are listed in the following table along with the applicable rules and/or requirements and with the applicable emissions limitations and/or control measures. Emissions from this unit shall not exceed the listed limitations, and the listed control measures shall be specified in narrative form following the table.

<u>Operations, Property, and/or Equipment</u>	<u>Applicable Rules/Requirements</u>	<u>Applicable Emissions Limitations/Control Measures</u>
P003 - Elution process (Room 300)		
VF-301-033 exhaust; Tanks T-320, T-321, T-322, Dissolver M-305, Poly Drum	OAC rule 3745-31-05(A)(3)	0.84 lb OC/hr, 2.42 TPY OC
	OAC rule 3745-21-07(G)	See T&C B.1.
		This emissions unit is exempt from the requirements of this rule. See term A.2.c.

**2. Additional Terms and Conditions**

- 2.a Compliance with OAC rule 3745-31-05(A)(3) shall be demonstrated by compliance with the annual operating hours operational restriction and compliance with the OC emissions limitations.
- 2.b The hourly emission limitation(s) outlined is based upon the emissions unit’s Potential to Emit (PTE). Therefore, no hourly records are required to demonstrate compliance with this limit.
- 2.c The use of photochemically reactive material as defined in OAC rule 3745-21-01(C)(5) is prohibited.

**B. Operational Restrictions**

1. The maximum annual operating hours for emissions unit P003, when emissions are being generated from the use of SDA-3A alcohol, shall not exceed 5760 hours per year.

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**PTI A**

**Issued: 4/8/2004**

Emissions Unit ID: **P003**

### C. Monitoring and/or Recordkeeping Requirements

1. The permittee shall maintain daily records of the following information for emissions unit P003:
  - a. a record of the operating hours for this emissions unit; and
  - b. a record of each liquid organic material employed in this emissions unit indicating, whether or not the liquid organic material is photochemically reactive as identified in OAC rule 3745-21-01(C)(5).
2. The permit to install for emissions units P003, P004 and P005, combined, was evaluated based on the actual materials (typically coatings and cleanup materials) and the design parameters of the emissions unit's exhaust system, as specified by the permittee in the permit to install application. The Ohio EPA's "Review of New Sources of Air Toxic Emissions" policy("Air Toxic Policy") was applied for each pollutant emitted by this emissions unit using data from the permit to install application and the SCREEN 3.0 model(or other Ohio EPA approved model). The predicted 1-hour maximum ground-level concentration from the use of the SCREEN 3.0 model was compared to the Maximum Ground-Level Concentration (MAGLC).

The following summarizes the results of the modeling for the "worst case" pollutant(s):

Pollutant: Methanol  
TLV (ug/m3): 262,000  
Maximum Hourly Emission Rate (lbs/hr): 0.84  
Predicted 1-Hour Maximum Ground-Level  
Concentration (ug/m3): 350  
MAGLC (ug/m3): 6240

Pollutant: Ethanol  
TLV (ug/m3): 1,881,000  
Maximum Hourly Emission Rate (lbs/hr): 15.66  
Predicted 1-Hour Maximum Ground-Level  
Concentration (ug/m3): 6602  
MAGLC (ug/m3): 44,800

Physical changes to or in the method of operation of the emissions unit after it's installation or modification could affect the parameters used to determine whether or not the "Air Toxics Policy" is satisfied. Consequently, prior to making a change that could impact such parameters, the permittee shall conduct an evaluation to determine that the "Air Toxic Policy" will still be satisfied. If, upon evaluation, the permittee determines that the "Air Toxic Policy" will not be

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**PTI A**

**Issued: 4/8/2004**

Emissions Unit ID: **P003**

satisfied, the permittee will not make the change. Changes that can affect the parameters used in the "Air Toxic Policy" include the following:

Emissions Unit ID: P003

- a. Changes in the composition of the materials used (typically for coatings or cleanup materials), or the use of new materials, that would result in the emission of a compound with a lower Threshold Limit Value (TLV), as indicated in the most recent version of the handbook entitled "American Conference of Governmental Industrial Hygienists (ACGIH)," than the lowest TLV value previously modeled;
- b. Changes in the composition of the materials, or use of new materials, that would result in an increase in emissions of any pollutant with a listed TLV that was proposed in the application and modeled; and
- c. Physical changes to the emissions unit or its exhaust parameters (e.g., increased/decreased exhaust flow, changes in stack height, changes in stack diameter, etc.).

If the permittee determines that the "Air Toxic Policy" will be satisfied with the above changes, the Ohio EPA will not consider the change(s) to be a "modification" under OAC rule 3745-31-01(VV)(1)(a)(ii), and a modification of the existing permit to install will not be required. If the change(s) is(are) defined as a modification under other provisions of the modification definition [other than (VV)(1)(a)(ii)], then the permittee shall obtain a final permit to install prior to the change.

The permittee shall collect, record, and retain the following information when it conducts evaluations to determine that the changed emissions unit will satisfy the Air Toxic Policy:"

- a. A description of the parameters changed (composition of materials, new pollutants emitted, change in stack/exhaust parameters, etc.);
- b. Documentation of its evaluation and determination that the changed emissions unit still satisfies the "Air Toxic Policy"; and
- c. When the computer modeling is performed, a copy of the resulting computer model runs that show the results of the application of the "Air Toxic Policy" for the change.

#### **D. Reporting Requirements**

1. The permittee shall submit annual deviation (excursion) reports to the Hamilton County Department of Environmental Services which identify any exceedances of the annual operating hours limitation, as well as the corrective actions that were taken to achieve compliance. If no deviations occurred during the reporting period, the permittee shall state so in the report. The permittee shall submit the reports by January 31 of each year and shall cover the previous calendar year.

2. The permittee shall submit annual reports which specify the total OC emissions from emissions unit P003 for the previous calendar year. The permittee shall submit the reports to the Hamilton County Department of Environmental Services by January 31 of each year and shall cover the previous calendar year.
3. The permittee shall notify the Hamilton County Department of Environmental Services in writing identifying each day during which any photochemically reactive material [as defined in OAC rule 3745-21-01(C)(5)] was employed in this emissions unit. This report shall identify the cause for the use of the photochemically reactive material(s) and the estimated total quantity of organic compound emissions emitted each such day. This report shall be submitted to the Hamilton County Department of Environmental Services within 45 days after the exceedance occurs.
4. The permittee shall notify the Hamilton County Department of Environmental Services in writing if the percentage of methanol in the SDA-3A exceeds that which is outlined in PTI application 14-05511. This report shall be submitted to the Hamilton County Department of Environmental Services within 45 days after the exceedance occurs.

#### **E. Testing Requirements**

1. Emissions Limitations

0.84 lb OC/hr from the elution VF-301-033 exhaust

Applicable Compliance Method

The permittee shall conduct, or have conducted, emission testing for this emissions unit in accordance with the following requirements:

- a. The emissions testing shall be conducted within nine (9) months after issuance of this permit;
- b. The emission testing shall be conducted to demonstrate compliance with the allowable mass emission rates for organic compounds (ethanol and methanol);
- c. The following test methods shall be employed to demonstrate compliance with the allowable mass emission rates: for organic compounds, Method 25 or Method 25A of 40 CFR Part 60, Appendix A. Alternative U.S. EPA approved test methods may be used with prior approval from the Hamilton County Department of Environmental Services; and

- d. The tests shall be conducted while the emissions unit is operating at or near its maximum capacity, unless otherwise specified or approved by the Hamilton County Department of Environmental Services.

Not later than 30 days prior to the proposed test date(s), the permittee shall submit an "Intent to Test" notification to the Hamilton County Department of Environmental Services. The "Intent to Test" notification shall describe in detail the proposed test methods and procedures, the emissions unit operating parameters, the time(s) and date(s) of the test(s), and the person(s) who will be conducting the test(s). Failure to submit such notification for review and approval prior to the test(s) may result in the Hamilton County Department of Environmental Services refusal to accept the results of the emission test(s).

Personnel from the Hamilton County Department of Environmental Services shall be permitted to witness the test(s), examine the testing equipment, and acquire data and information necessary to ensure that the operation of the emissions unit and the testing procedures provide a valid characterization of the emissions from the emissions unit and/or the performance of the control equipment.

A comprehensive written report on the results of the emissions test(s) shall be signed by the person or persons responsible for the tests and submitted to the Hamilton County Department of Environmental Services within 30 days following completion of the test(s). The permittee may request additional time for the submittal of the written report, where warranted, with prior approval from the Hamilton County Department of Environmental Services.

2. Emissions Limitations

2.42 TPY OC from the elution VF-301-033 exhaust

Applicable Compliance Method

Compliance with the annual OC emissions limitations shall be demonstrated by the following:

multiplying the "emissions factor", the lbs OC/hr emissions as measured in the latest emissions test of the VF-301-033 exhaust pursuant to T&C E.1., by the actual annual production schedule, in hours/year, of the previous calendar year for the Elution Process. The permittee shall divide by 2000 so that the product equals TPY OC.

3. Compliance with the hours of operation limitation in term B.1 shall be demonstrated by the record keeping in term C.1.

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**PTI A**

**Issued: 4/8/2004**

Emissions Unit ID: **P003**

**F. Miscellaneous Requirements**

None

**PART II - SPECIAL TERMS AND CONDITIONS FOR SPECIFIC EMISSIONS UNIT(S)**

**A. Applicable Emissions Limitations and/or Control Requirements**

1. The specific operations(s), property, and/or equipment which constitute this emissions unit are listed in the following table along with the applicable rules and/or requirements and with the applicable emissions limitations and/or control measures. Emissions from this unit shall not exceed the listed limitations, and the listed control measures shall be specified in narrative form following the table.

<u>Operations, Property, and/or Equipment</u>	<u>Applicable Rules/Requirements</u>	<u>Applicable Emissions Limitations/Control Measures</u>
P004 - Purification No. 1 process (Room 205)		
VF-400-120 exhaust; Tanks T-201, T-202, T-203, T-204, T-205, Poly Drum, Exhaust Grille	OAC rule 3745-31-05(A)(3)	13.19 lbs OC/hr, 25.33 TPY OC  See T&C B.1.
	OAC rule 3745-21-07(G)	The emissions unit is exempt from the requirements of this rule. See term A.2.c.

**2. Additional Terms and Conditions**

- 2.a Compliance with OAC rule 3745-31-05(A)(3) shall be demonstrated by compliance with the annual operating hours operational restriction and compliance with the OC emissions limitations.
- 2.b The hourly emission limitation(s) outlined is based upon the emissions unit's Potential to Emit (PTE). Therefore, no hourly records are required to demonstrate compliance with this limit.
- 2.c The use of photochemically reactive material as defined in OAC rule 3745-21-01(C)(5) is prohibited.

**B. Operational Restrictions**

**Pharmacia Hepar Inc**  
**PTI Application: 14-05511**  
**Issued**

**Facility ID: 1483040192**

Emissions Unit ID: **P004**

1. The maximum annual operating hours for emissions unit P004, when emissions are being generated from the use of SDA-3A alcohol, shall not exceed 3840 hours per year.

**C. Monitoring and/or Recordkeeping Requirements**

1. The permittee shall maintain daily records of the following information for emissions unit P004:
  - a. a record of the operating hours for this emissions unit; and
  - b. a record of each liquid organic material employed in this emissions unit indicating, whether or not the liquid organic material is photochemically reactive as identified in OAC rule 3745-21-01(C)(5).
2. The permit to install for emissions units P003, P004 and P005, combined, was evaluated based on the actual materials (typically coatings and cleanup materials) and the design parameters of the emissions unit's exhaust system, as specified by the permittee in the permit to install application. The Ohio EPA's "Review of New Sources of Air Toxic Emissions" policy("Air Toxic Policy") was applied for each pollutant emitted by this emissions unit using data from the permit to install application and the SCREEN 3.0 model(or other Ohio EPA approved model). The predicted 1-hour maximum ground-level concentration from the use of the SCREEN 3.0 model was compared to the Maximum Ground-Level Concentration (MAGLC).

The following summarizes the results of the modeling for the "worst case" pollutant(s):

Pollutant: Methanol

TLV (ug/m3): 262,000

Maximum Hourly Emission Rate (lbs/hr): 0.84

Predicted 1-Hour Maximum Ground-Level

Concentration (ug/m3): 350

MAGLC (ug/m3): 6240

Pollutant: Ethanol

TLV (ug/m3): 1,881,000

Maximum Hourly Emission Rate (lbs/hr): 15.66

Predicted 1-Hour Maximum Ground-Level

Concentration (ug/m3): 6602

MAGLC (ug/m3): 44,800

Physical changes to or in the method of operation of the emissions unit after it's installation or modification could affect the parameters used to determine whether or not the "Air Toxics Policy" is satisfied. Consequently, prior to making a change that could impact such parameters, the permittee shall conduct an evaluation to determine that the "Air Toxic Policy" will still be satisfied. If, upon evaluation, the permittee determines that the "Air Toxic Policy" will not be

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**PTI A**

**Issued: 4/8/2004**

Emissions Unit ID: **P004**

satisfied, the permittee will not make the change. Changes that can affect the parameters used in the "Air Toxic Policy" include the following:

- a. Changes in the composition of the materials used (typically for coatings or cleanup materials), or the use of new materials, that would result in the emission of a compound with a lower Threshold Limit Value (TLV), as indicated in the most recent version of the handbook entitled "American Conference of Governmental Industrial Hygienists (ACGIH)," than the lowest TLV value previously modeled;
- b. Changes in the composition of the materials, or use of new materials, that would result in an increase in emissions of any pollutant with a listed TLV that was proposed in the application and modeled; and
- c. Physical changes to the emissions unit or its exhaust parameters (e.g., increased/decreased exhaust flow, changes in stack height, changes in stack diameter, etc.).

If the permittee determines that the "Air Toxic Policy" will be satisfied with the above changes, the Ohio EPA will not consider the change(s) to be a "modification" under OAC rule 3745-31-01(VV)(1)(a)(ii), and a modification of the existing permit to install will not be required. If the change(s) is(are) defined as a modification under other provisions of the modification definition [other than (VV)(1)(a)(ii)], then the permittee shall obtain a final permit to install prior to the change.

The permittee shall collect, record, and retain the following information when it conducts evaluations to determine that the changed emissions unit will satisfy the Air Toxic Policy:"

- a. A description of the parameters changed (composition of materials, new pollutants emitted, change in stack/exhaust parameters, etc.);
- b. Documentation of its evaluation and determination that the changed emissions unit still satisfies the "Air Toxic Policy"; and
- c. When the computer modeling is performed, a copy of the resulting computer model runs that show the results of the application of the "Air Toxic Policy" for the change.

#### **D. Reporting Requirements**

1. The permittee shall submit annual deviation (excursion) reports to the Hamilton County Department of Environmental Services which identify any exceedances of the annual operating hours limitation, as well as the corrective actions that were taken to achieve compliance. If no deviations occurred during the reporting period, the permittee shall state so in the report. The permittee shall submit the reports by January 31 of each year and shall cover the previous calendar year.

2. The permittee shall submit annual reports which specify the total OC emissions from emissions unit P004 for the previous calendar year. The permittee shall submit the reports to the Hamilton County Department of Environmental Services by January 31 of each year and shall cover the previous calendar year.
3. The permittee shall notify the Hamilton County Department of Environmental Services in writing identifying each day during which any photochemically reactive material [as defined in OAC rule 3745-21-01(C)(5)] was employed in this emissions unit. This report shall identify the cause for the use of the photochemically reactive material(s) and the estimated total quantity of organic compound emissions emitted each such day. This report shall be submitted to the Hamilton County Department of Environmental Services within 45 days after the exceedance occurs.
4. The permittee shall notify the Hamilton County Department of Environmental Services in writing if the percentage of methanol in the SDA-3A exceeds that which is outlined in PTI application 14-05511. This report shall be submitted to the Hamilton County Department of Environmental Services within 45 days after the exceedance occurs.

#### **E. Testing Requirements**

1. Emissions Limitation

13.19 lbs OC/hr from the purification #1 VF-400-120 exhaust

##### Applicable Compliance Method

The permittee shall conduct, or have conducted, emission testing for this emissions unit in accordance with the following requirements:

- a. The emissions testing shall be conducted within nine (9) months after issuance of this permit;
- b. The emission testing shall be conducted to demonstrate compliance with the allowable mass emission rates for organic compounds (ethanol and methanol);
- c. The following test methods shall be employed to demonstrate compliance with the allowable mass emission rates: for organic compounds, Method 25 or Method 25A of 40 CFR Part 60, Appendix A. Alternative U.S. EPA approved test methods may be used with prior approval from the Hamilton County Department of Environmental Services; and

- d. The tests shall be conducted while the emissions unit is operating at or near its maximum capacity, unless otherwise specified or approved by the Hamilton County Department of Environmental Services.

Not later than 30 days prior to the proposed test date(s), the permittee shall submit an "Intent to Test" notification to the Hamilton County Department of Environmental Services. The "Intent to Test" notification shall describe in detail the proposed test methods and procedures, the emissions unit operating parameters, the time(s) and date(s) of the test(s), and the person(s) who will be conducting the test(s). Failure to submit such notification for review and approval prior to the test(s) may result in the Hamilton County Department of Environmental Services refusal to accept the results of the emission test(s).

Personnel from the Hamilton County Department of Environmental Services shall be permitted to witness the test(s), examine the testing equipment, and acquire data and information necessary to ensure that the operation of the emissions unit and the testing procedures provide a valid characterization of the emissions from the emissions unit and/or the performance of the control equipment.

A comprehensive written report on the results of the emissions test(s) shall be signed by the person or persons responsible for the tests and submitted to the Hamilton County Department of Environmental Services within 30 days following completion of the test(s). The permittee may request additional time for the submittal of the written report, where warranted, with prior approval from the Hamilton County Department of Environmental Services.

## 2. Emissions Limitations

25.33 TPY OC from the purification VF-400-120 exhaust

Applicable Compliance Method

Compliance with the annual OC emissions limitations shall be demonstrated by the following:

multiplying the "emissions factor", the lbs OC/hr emissions as measured in the latest emissions test of the VF-400-120 exhaust pursuant to T&C E.1., by the actual annual production schedule, in hours/year, of the previous calendar year for the Purification No.1 Process. The permittee shall divide by 2000 so that the product equals TPY OC.

3. Compliance with the hours of operation limitation in term B.1 shall be demonstrated by the record keeping in term C.1.

**Pharmacia Hepar Inc**  
**PTI Application: 14-05511**  
**Issued**

**Facility ID: 1483040192**

Emissions Unit ID: **P004**

**F. Miscellaneous Requirements**

None

**PART II - SPECIAL TERMS AND CONDITIONS FOR SPECIFIC EMISSIONS UNIT(S)****A. Applicable Emissions Limitations and/or Control Requirements**

1. The specific operations(s), property, and/or equipment which constitute this emissions unit are listed in the following table along with the applicable rules and/or requirements and with the applicable emissions limitations and/or control measures. Emissions from this unit shall not exceed the listed limitations, and the listed control measures shall be specified in narrative form following the table.

<u>Operations, Property, and/or Equipment</u>	<u>Applicable Rules/Requirements</u>	<u>Applicable Emissions Limitations/Control Measures</u>
P005 - Purification No. 2 process (Room 212)		
VF-405-044 Exhaust; Tanks T-207 and T-208, Dissolvers D-201 and D-202, Poly Drum, Slot Hood (low level), Exhaust Grille	OAC rule 3745-31-05(A)(3)	2.47 lbs OC/hr, 9.95 TPY OC
	OAC rule 3745-21-07(G)	See T&C B.1. The emissions unit is exempt from the requirements of this rule. See term A.2.c.

**2. Additional Terms and Conditions**

- 2.a** Compliance with OAC rule 3745-31-05(A)(3) shall be demonstrated by compliance with the annual operating hours operational restriction and compliance with the OC emissions limitations.
- 2.b** The hourly emission limitation(s) outlined is based upon the emissions unit's Potential to Emit (PTE). Therefore, no hourly records are required to demonstrate compliance with this limit.
- 2.c** The use of photochemically reactive material as defined in OAC rule 3745-21-01(C)(5) is prohibited.

**B. Operational Restrictions**

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1. The maximum annual operating hours for emissions unit P005, when emissions are being generated from the use of SDA-3A alcohol, shall not exceed 8064 hours per year.

**C. Monitoring and/or Recordkeeping Requirements**

1. The permittee shall maintain daily records of the following information for emissions unit P005:
  - a. a record of the operating hours for this emissions unit; and
  - b. a record of each liquid organic material employed in this emissions unit indicating, whether or not the liquid organic material is photochemically reactive as identified in OAC rule 3745-21-01(C)(5).
2. The permit to install for emissions units P003, P004 and P005, combined, was evaluated based on the actual materials (typically coatings and cleanup materials) and the design parameters of the emissions unit's exhaust system, as specified by the permittee in the permit to install application. The Ohio EPA's "Review of New Sources of Air Toxic Emissions" policy("Air Toxic Policy") was applied for each pollutant emitted by this emissions unit using data from the permit to install application and the SCREEN 3.0 model(or other Ohio EPA approved model). The predicted 1-hour maximum ground-level concentration from the use of the SCREEN 3.0 model was compared to the Maximum Ground-Level Concentration (MAGLC).

The following summarizes the results of the modeling for the "worst case" pollutant(s):

Pollutant: Methanol

TLV (ug/m3): 262,000

Maximum Hourly Emission Rate (lbs/hr): 0.84

Predicted 1-Hour Maximum Ground-Level

Concentration (ug/m3): 350

MAGLC (ug/m3): 6240

Pollutant: Ethanol

TLV (ug/m3): 1,881,000

Maximum Hourly Emission Rate (lbs/hr): 15.66

Predicted 1-Hour Maximum Ground-Level

Concentration (ug/m3): 6602

MAGLC (ug/m3): 44,800

Physical changes to or in the method of operation of the emissions unit after it's installation or modification could affect the parameters used to determine whether or not the "Air Toxics Policy" is satisfied. Consequently, prior to making a change that could impact such parameters, the permittee shall conduct an evaluation to determine that the "Air Toxic Policy" will still be satisfied. If, upon evaluation, the permittee determines that the "Air Toxic Policy" will not be

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satisfied, the permittee will not make the change. Changes that can affect the parameters used in the "Air Toxic Policy" include the following:

- a. Changes in the composition of the materials used (typically for coatings or cleanup materials), or the use of new materials, that would result in the emission of a compound with a lower Threshold Limit Value (TLV), as indicated in the most recent version of the handbook entitled "American Conference of Governmental Industrial Hygienists (ACGIH)," than the lowest TLV value previously modeled;
- b. Changes in the composition of the materials, or use of new materials, that would result in an increase in emissions of any pollutant with a listed TLV that was proposed in the application and modeled; and
- c. Physical changes to the emissions unit or its exhaust parameters (e.g., increased/decreased exhaust flow, changes in stack height, changes in stack diameter, etc.).

If the permittee determines that the "Air Toxic Policy" will be satisfied with the above changes, the Ohio EPA will not consider the change(s) to be a "modification" under OAC rule 3745-31-01(VV)(1)(a)(ii), and a modification of the existing permit to install will not be required. If the change(s) is(are) defined as a modification under other provisions of the modification definition [other than (VV)(1)(a)(ii)], then the permittee shall obtain a final permit to install prior to the change.

The permittee shall collect, record, and retain the following information when it conducts evaluations to determine that the changed emissions unit will satisfy the Air Toxic Policy:"

- a. A description of the parameters changed (composition of materials, new pollutants emitted, change in stack/exhaust parameters, etc.);
- b. Documentation of its evaluation and determination that the changed emissions unit still satisfies the "Air Toxic Policy"; and
- c. When the computer modeling is performed, a copy of the resulting computer model runs that show the results of the application of the "Air Toxic Policy" for the change.

#### **D. Reporting Requirements**

1. The permittee shall submit annual deviation (excursion) reports to the Hamilton County Department of Environmental Services which identify any exceedances of the annual operating hours limitation, as well as the corrective actions that were taken to achieve compliance. If no deviations occurred during the reporting period, the permittee shall state so in the report. The permittee shall submit the reports by January 31 of each year and shall cover the previous calendar year.

2. The permittee shall submit annual reports which specify the total OC emissions from emissions unit P005 for the previous calendar year. The permittee shall submit the reports to the Hamilton County Department of Environmental Services by January 31 of each year and shall cover the previous calendar year.
3. The permittee shall notify the Hamilton County Department of Environmental Services in writing identifying each day during which any photochemically reactive material [as defined in OAC rule 3745-21-01(C)(5)] was employed in this emissions unit. This report shall identify the cause for the use of the photochemically reactive material(s) and the estimated total quantity of organic compound emissions emitted each such day. This report shall be submitted to the Hamilton County Department of Environmental Services within 45 days after the exceedance occurs.
4. The permittee shall notify the Hamilton County Department of Environmental Services in writing if the percentage of methanol in the SDA-3A exceeds that which is outlined in PTI application 14-05511. This report shall be submitted to the Hamilton County Department of Environmental Services within 45 days after the exceedance occurs.

#### **E. Testing Requirements**

1. Emissions Limitations

2.47 lbs OC/hr from the purification #2 VF-405-044 exhaust

Applicable Compliance Method

The permittee shall conduct, or have conducted, emission testing for this emissions unit in accordance with the following requirements:

- a. The emissions testing shall be conducted within nine (9) months after issuance of this permit;
- b. The emission testing shall be conducted to demonstrate compliance with the allowable mass emission rates for organic compounds (ethanol and methanol);
- c. The following test methods shall be employed to demonstrate compliance with the allowable mass emission rates: for organic compounds, Method 25 or Method 25A of 40 CFR Part 60, Appendix A. Alternative U.S. EPA approved test methods may be used with prior approval from the Hamilton County Department of Environmental Services; and

- d. The tests shall be conducted while the emissions unit is operating at or near its maximum capacity, unless otherwise specified or approved by the Hamilton County Department of Environmental Services.

Not later than 30 days prior to the proposed test date(s), the permittee shall submit an "Intent to Test" notification to the Hamilton County Department of Environmental Services. The "Intent to Test" notification shall describe in detail the proposed test methods and procedures, the emissions unit operating parameters, the time(s) and date(s) of the test(s), and the person(s) who will be conducting the test(s). Failure to submit such notification for review and approval prior to the test(s) may result in the Hamilton County Department of Environmental Services refusal to accept the results of the emission test(s).

Personnel from the Hamilton County Department of Environmental Services shall be permitted to witness the test(s), examine the testing equipment, and acquire data and information necessary to ensure that the operation of the emissions unit and the testing procedures provide a valid characterization of the emissions from the emissions unit and/or the performance of the control equipment.

A comprehensive written report on the results of the emissions test(s) shall be signed by the person or persons responsible for the tests and submitted to the Hamilton County Department of Environmental Services within 30 days following completion of the test(s). The permittee may request additional time for the submittal of the written report, where warranted, with prior approval from the Hamilton County Department of Environmental Services.

2. Emissions Limitations

9.95 TPY OC from the purification VF-405-044 exhaust

Applicable Compliance Method

Compliance with the annual OC emissions limitations shall be demonstrated by the following:

multiplying the "emissions factor", the lbs OC/hr emissions as measured in the latest emissions test of the VF-405-044 exhaust pursuant to T&C E.1., by the actual annual production schedule, in hours/year, of the previous calendar year for the Purification No.2 Process. The permittee shall divide by 2000 so that the product equals TPY OC.

3. Compliance with the hours of operation limitation in term B.1 shall be demonstrated by the record keeping in term C.1.

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**F. Miscellaneous Requirements**

None