



Mitchell E. Daniels, Jr.
Governor

Thomas W. Easterly
Commissioner

100 North Senate Avenue
Indianapolis, Indiana 46204
(317) 232-8603
(800) 451-6027
www.IN.gov/idem

TO: Interested Parties / Applicant
DATE: December 5, 2007
RE: MonoSol Rx / 127-25431-00114
FROM: Matthew Stuckey, Deputy Branch Chief
Permits Branch
Office of Air Quality

Notice of Decision: Approval - Effective Immediately

Please be advised that on behalf of the Commissioner of the Department of Environmental Management, I have issued a decision regarding the enclosed matter. Pursuant to IC 13-15-5-3, this permit is effective immediately, unless a petition for stay of effectiveness is filed and granted according to IC 13-15-6-3, and may be revoked or modified in accordance with the provisions of IC 13-15-7-1.

If you wish to challenge this decision, IC 4-21.5-3 and IC 13-15-6-1 require that you file a petition for administrative review. This petition may include a request for stay of effectiveness and must be submitted to the Office of Environmental Adjudication, 100 North Senate Avenue, Government Center North, Suite N 501E, Indianapolis, IN 46204, **within eighteen (18) calendar days of the mailing of this notice**. The filing of a petition for administrative review is complete on the earliest of the following dates that apply to the filing:

- (1) the date the document is delivered to the Office of Environmental Adjudication (OEA);
- (2) the date of the postmark on the envelope containing the document, if the document is mailed to OEA by U.S. mail; or
- (3) The date on which the document is deposited with a private carrier, as shown by receipt issued by the carrier, if the document is sent to the OEA by private carrier.

The petition must include facts demonstrating that you are either the applicant, a person aggrieved or adversely affected by the decision or otherwise entitled to review by law. Please identify the permit, decision, or other order for which you seek review by permit number, name of the applicant, location, date of this notice and all of the following:

- (1) the name and address of the person making the request;
- (2) the interest of the person making the request;
- (3) identification of any persons represented by the person making the request;
- (4) the reasons, with particularity, for the request;
- (5) the issues, with particularity, proposed for considerations at any hearing; and
- (6) identification of the terms and conditions which, in the judgment of the person making the request, would be appropriate in the case in question to satisfy the requirements of the law governing documents of the type issued by the Commissioner.

If you have technical questions regarding the enclosed documents, please contact the Office of Air Quality, Permits Branch at (317) 233-0178. Callers from within Indiana may call toll-free at 1-800-451-6027, ext. 3-0178.

Enclosures
FNPER.dot12/03/07



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MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251
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SOURCE SPECIFIC OPERATING AGREEMENT OFFICE OF AIR QUALITY

MonoSol Rx
6465 Ameriplex Drive and 6560 Melton Road
Portage, Indiana 46368

(herein known as the Permittee) is hereby authorized to operate subject to the conditions contained herein, the source described in Section A (Source Summary) of this SSOA.

This SSOA is issued to the above mentioned company under the provisions of 326 IAC 2-1.1, 326 IAC 2-9 and 40 CFR 52.780, with conditions listed on the attached pages.

Indiana statutes from IC 13 and rules from 326 IAC, quoted in conditions in this SSOA, are those applicable at the time the SSOA was issued. The issuance or possession of this SSOA shall not alone constitute a defense against an alleged violation of any law, regulation or standard, except for the requirement to obtain a Source Specific Operating Agreement (SSOA) under 326 IAC 2-9.

Source Specific Operating Agreement No. 127-25431-00114	
Issued by: <i>Original signed by Matt Stuckey for</i> Iryn Calilung, Section Chief Permits Branch Office of Air Quality	Issuance Date: December 5, 2007

SECTION A

SOURCE SUMMARY

This SSOA is based on information requested by the Indiana Department of Environmental Management (IDEM), Office of Air Quality (OAQ). The information describing the source contained in conditions A.1 and A.2 is descriptive information and does not constitute enforceable conditions. However, the Permittee should be aware that a physical change or a change in the method of operation that may render this descriptive information obsolete or inaccurate may trigger requirements for the Permittee to obtain additional permits pursuant to 326 IAC 2.

A.1 General Information

The Permittee owns and operates a stationary pharmaceutical water-soluble thin film manufacturing source.

Source Address:	6465 Ameriplex Drive, Portage and 6560 Melton Road, Portage IN 46368
Mailing Address:	6560 Melton Road, Portage, IN 46368
General Source Phone Number:	219-762-8112
SIC Code:	2834
County Location:	Porter County
Source Location Status:	Nonattainment for 8-hour and 1-hour ozone standards Nonattainment for PM2.5 standard Attainment for all other criteria pollutants
Source Status:	Source Specific Operating Agreement (SSOA) Not 1 of 28 Source Categories

A.2 Source Definition

This stationary pharmaceutical water-soluble thin film manufacturing source consists of two (2) plants:

- (a) MonoSol Rx Melton Road, Plant ID No. 127-00110, located at 6560 Melton Road, Portage, IN; and
- (b) MonoSol Rx Ameriplex Drive, Plant ID No. 127-00114, located at 6465 Ameriplex Drive, Portage, IN.

Since the two (2) plants are located on contiguous or adjacent properties, belong to the same industrial grouping, support one another, and are under common control of the same entity, they will be considered one (1) source, effective from the date of issuance of this SSOA.

A.3 Source Summary

This stationary source consists of the following:

- (a) Surface Coating or Graphic Arts Operation [326 IAC 2-9-2.5]
- (b) External Combustion Sources [326 IAC 2-9-13]
- (c) Internal Combustion Sources [326 IAC 2-9-14]

A.4 SSOA Applicability [326 IAC 2-9-1]

- (a) This stationary source, otherwise required to have a Part 70 permit as described in 326 IAC 2-7-2(a), has applied to the Indiana Department of Environmental Management (IDEM), Office of Air Quality (OAQ) for a Source Specific Operating Agreement (SSOA).
- (b) Pursuant to 326 IAC 2-9-1(g), the source may apply for up to four (4) different SSOAs contained in 326 IAC 2-9.

SECTION B

GENERAL CONDITIONS

B.1 Prior Permits Superseded [326 IAC 2-1.1-9.5]

- (a) All terms and conditions of permits established prior to SSOA No. 127-25431-00114 and issued pursuant to permitting programs approved into the state implementation plan have been either:
- (1) incorporated as originally stated,
 - (2) revised, or
 - (3) deleted.
- (b) All previous registrations and permits are superseded by this permit.

B.2 Annual Notification [326 IAC 2-9-1(d)]

Pursuant to 326 IAC 2-9-1(d):

- (a) An annual notification shall be submitted by an authorized individual to the Office of Air Quality stating whether or not the source is in operation and in compliance with the terms and conditions contained in this SSOA.
- (b) The annual notice shall be submitted in the format attached no later than January 30 of each year to:
- Indiana Department of Environmental Management
Compliance Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, IN 46204-2251
- (c) The notification shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ on or before the date it is due.

B.3 Source Modification Requirement [326 IAC 2-9-1(e)]

Pursuant to 326 IAC 2-9-1(e), any change or modification which will alter operations in such a way that it will no longer comply with the applicable restrictions and conditions of this operating agreement, must obtain the appropriate approval from the Office of Air Quality (OAQ) under 326 IAC 2-5.1, 326 IAC 2-5.5, 326 IAC 2-6.1, 326 IAC 2-2, 326 IAC 2-3, 326 IAC 2-7, and 326 IAC 2-8, before such change may occur.

B.4 General Record Keeping Requirements [326 IAC 2-9-1(f)]

Pursuant to 326 IAC 2-9-1(f), records of all required monitoring data, reports and support information required by this SSOA shall be physically present or electronically accessible at the source location for a period of at least five (5) years from the date of monitoring sample, measurement, report, or application. If the Commissioner makes a request for records to the Permittee, the Permittee shall furnish the records to the Commissioner within a reasonable time.

B.5 Reporting Requirements [326 IAC 2-9-1(h)]

Pursuant to 326 IAC 2-9-1(h), any exceedance of any requirement contained in this operating agreement shall be reported, in writing, within one (1) week of its occurrence. Said report shall include information on the actions taken to correct the exceedance, including measures to reduce emissions, in order to comply with the established limits. If an exceedance is the result of a malfunction, then the provisions of 326 IAC 1-6 apply.

B.6 Compliance with Applicable Requirements [326 IAC 2-9-1(i)]

Pursuant to 326 IAC 2-9-1(i), the owner or operator is hereby notified that this operating agreement does not relieve the permittee of the responsibility to comply with the provisions of any applicable federal, state, or local rules, or any New Source Performance Standards (NSPS), 40 CFR Part 60, or National Emission Standards for Hazardous Air Pollutants (NESHAP), 40 CFR Part 61 or 40 CFR Part 63.

B.7 SSOA Revocation [326 IAC 2-9-1(j)]

Pursuant to 326 IAC 2-9-1(j), noncompliance with any applicable provision 326 IAC 2-9 or any requirement contained in this SSOA may result in the revocation of this SSOA and make this source subject to the applicable requirements of a major source.

SECTION C

OPERATION CONDITIONS

Operation Description: Surface Coating or Graphic Arts Operation [326 IAC 2-9-2.5]

(The information describing the process contained in this emissions unit description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards

C.1 Volatile Organic Compounds and Hazardous Air Pollutants Limits [326 IAC 2-9-2.5(b)(2)(B)]

Pursuant to 326 IAC 2-9-2.5(b)(2)(B), the total amount of volatile organic compounds (VOC) and hazardous air pollutants (HAP), as supplied, delivered to the surface coating operation shall not exceed the following:

- (a) the total amount of VOC shall not exceed two (2) tons per month,
- (b) the total amount of any single HAP shall not exceed eight hundred thirty-three (833) pounds per month, and
- (c) the total amount of any combination of HAP shall not exceed one (1) ton per month.

C.2 Particulate [326 IAC 2-9-2.5(b)(5)]

Pursuant to 326 IAC 2-9-2.5(b)(5), particulate matter emissions shall be controlled by a dry filter system or an equivalent control device. The source shall operate the particulate control device at all times the surface coating operation is in operation in accordance with the manufacturer's specifications. A source shall be considered in compliance with this requirement provided the overspray is not visibly detectable at the exhaust or accumulated on the rooftops or on the ground.

Record Keeping and Reporting Requirements

C.3 Record Keeping Requirements [326 IAC 2-9-2.5(b)(3)]

Pursuant to 326 IAC 2-9-2.5(b)(3), the source shall keep the following records of the surface coating operation:

- (a) the number of gallons of each solvent containing material used,
- (b) the VOC and HAP content (pounds per gallon, as supplied) of each solvent containing material used,
- (c) material safety data sheets (MSDS) for each solvent containing material used,
- (d) a monthly summation of VOC and HAP usage, and
- (e) purchase orders and invoices for each solvent containing material used.

All records shall be maintained in accordance with Condition B.4 - General Record Keeping Requirements.

C.4 Reporting Requirements [326 IAC 2-9-2.5(b)(6)]

Pursuant to 326 IAC 2-9-2.5(b)(6), the Permittee shall include with the annual notice required in Section B - Annual Notification, an inventory listing of the monthly volatile organic compound (VOC) and hazardous air pollutant (HAP) totals, and the total VOC and HAP emissions for the previous twelve (12) months.

SECTION D

OPERATION CONDITIONS

Operation Description: External Combustion Sources [326 IAC 2-9-13]

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards

D.1 External Combustion Sources Limitations [326 IAC 2-9-13(b)(2)(A)] [326 IAC 2-9-13(c)]

- (a) Pursuant to 326 IAC 2-9-13(b)(2)(A), the fuel usage for the external combustion units at this source shall be limited to less than seven hundred fourteen million cubic feet (714 MMcf) of natural gas per twelve (12) consecutive month period.

- (b) Pursuant to 326 IAC 2-9-13(c), sources must be able to demonstrate compliance no later than thirty (30) days after receipt of a written request by the department or U.S. EPA. No other demonstration of compliance shall be required. A source specific operating agreement is not required for these sources.

D.2 Opacity [326 IAC 2-9-13(b)(1)]

Pursuant to 326 IAC 2-9-13(b)(1), the visible emissions from the source shall not exceed twenty percent (20%) opacity in twenty-four (24) consecutive readings in a six (6) minute period. The opacity shall be determined using 40 CFR 60, Appendix A, Method 9.

SECTION E

OPERATION CONDITIONS

Operation Description: Internal Combustion Sources [326 IAC 2-9-14]

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards

E.1 Internal Combustion Sources Limitation [326 IAC 2-9-14(a)(1)] [326 IAC 2-9-14(b)]

- (a) Pursuant to 326 IAC 2-9-14(a)(1), the fuel usage for internal combustion units at this source shall be limited to less than two hundred thirty-five and forty-five hundredths kilogallons (235.45 kgal) of diesel fuel per twelve (12) consecutive month period.
- (b) Pursuant to 326 IAC 2-9-14(b), sources must be able to demonstrate compliance no later than thirty (30) days after receipt of a written request by the department or U.S. EPA. No other demonstration of compliance shall be required. A source specific operating agreement is not required for these sources.

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE BRANCH**

**SOURCE SPECIFIC OPERATING AGREEMENT (SSOA)
ANNUAL NOTIFICATION**

This form should be used to comply with the notification requirements under 326 IAC 2-9.

Company Name:	MonoSol Rx
Address:	6465 Ameriplex Drive and 6560 Melton Road
City:	Portage, IN 46368
Phone #:	219-762-8112
SSOA #:	127-25431-00114

I hereby certify that MonoSol Rx is :

still in operation.

I hereby certify that MonoSol Rx is :

no longer in operation.

in compliance with the requirements
of SSOA 127-25431-00114.

not in compliance with the requirements
of SSOA 127-25431-00114.

Authorized Individual (typed):
Title:
Signature:
Date:

If there are any conditions or requirements for which the source is not in compliance, provide a narrative description of how the source did or will achieve compliance and the date compliance was, or will be achieved.

Noncompliance:

