



Commonwealth of Massachusetts
Executive Office of Energy & Environmental Affairs

Department of Environmental Protection

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May 31, 2013

Mr. James Sheppard
Covidien LP
2 Ludlow Park Drive
Chicopee, MA 01022

Re: PVAPCD – Chicopee
Regulation 310 CMR 7.02
Application No. WE-13-016
Transmittal No. X255432
New Process Line

FINAL APPROVAL

Dear Mr. Sheppard:

The Department of Environmental Protection, Western Region ("MassDEP"), on May 21, 2013, received a Limited Plan Application ("LPA") from Covidien LP located at 2 Ludlow Park Drive in Chicopee, MA. The LPA was submitted to obtain approval for the installation of Process No. 12 – Wide Web Gel Line. ***This Approval supercedes Approval # 1-P-10-029, dated 9/9/2010 and replaces that approval in full.***

INTRODUCTION

Covidien manufactures medical devices, medical chart paper and other medical products at the facility. The facility is currently operating under Approval # 1-P-10-029 for seven (7) different process lines. Current potential Hazardous Air Pollutant ("HAP") emissions will remain at 9.9 tons per year ("tpy") or less for a single HAP and at 24.9 tpy or less for total HAPs. The facility-wide emission limit for volatile organic compounds ("VOC") will be 32.6 tpy.

Process Line #12 In this application, Covidien is requesting the approval of Process No. 12 which is a gel formulating and casting operation. It is similar to the facility's existing Process No. 4 60's line.

In this process, hydrogel is laminated between two liners, which prevents it from drying out prior to use. The process includes a gel mixing operation, associated tanks and equipment, and a casting line to lay the gel into the substrate. The line will be built in-house and is one of a kind.

Air emissions are created in the gel mixing operation and the casting/UV curing operation due to the acrylic acid/isopropyl alcohol gel formulation and from VOC containing cleaners and lubricants. The gel formulation contains 3% acrylic acid and 97% isopropyl alcohol ("IPA").

Based on weight loss studies conducted at the facility, it has been determined that most of the acrylic acid is cured into the product with about 0.5% emitted. Based on a maximum daily usage rate of 21 lb/min, 0.5% acrylic acid emitted, and 365 operating days per year, the potential emissions of acrylic acid will be 0.82 tpy. Potential IPA emissions were determined based on a fixed ratio of IPA to acrylic acid determined from 2002 actual IPA and acrylic acid usage, as used in the 60's line. Potential IPA emissions so estimated will be 1.4 tpy. Soap and water are the primary cleaners with IPA used occasionally. Total cleaning solvent usage and emissions will be approximately 0.9 tpy.

Process line #2 ("691" line) is used to produce medical EKG electrodes for the medical industry. This process line consists of three stations, which uses conductive inks and UV technology. The first station is a UV cured flexographic printer that applies lettering to the clear plastic substrate. The second station is a screen-printing operation that applies conductive ink to the plastic. This ink is dried in an electric oven. The third station uses a UV cured gel adhesive that is applied over the ink. This process line was previously approved in Approval #1-P-03-023 with an emission limit of 8.5 tpy. The VOC content of the conductive inks is 55 percent by weight with an unrestricted potential to emit of 17.99 tpy. The VOC content of the UV cure on station 1 is 0.65 percent by weight with a potential to emit of 0.04 tpy and 13 percent by weight on station 3 with a tested emission rate of 0.36 tpy. Covidien proposes to limit the emissions to 12.0 tpy VOC as previously limited in MassDEP Approval #1-P-10-029.

Process line #3 produces Recording Charts. This process includes five printing presses (Presses # 4, 6, 7 are Goebel presses; presses #12 and 14 are Taiyo presses), five winders, and a pouching pack machine for making hot and cold packs. The printing presses use UV, water-based (flexo), and oil based inks. The presses and winders have end warnings and date markings that utilize small quantities (no more than 250 gallons per year) of solvent based inks ("specialty inks") that may be up to 100% VOC. VOCs are emitted from this operation due to the VOC in the inks, thinners and clean-up solvents. Unrestricted potential emissions from this process line are 29.17 tpy VOC. Covidien proposes to limit the emissions to 4.0 tpy VOC as previously limited in MassDEP Approval #1-P-10-029.

Process line #4 (60's, 70's, 80's Lines) is a coating and curing operation that produces hydrogel. Hydrogel is a water-borne UV cured compound that contains some VOCs. The materials used for cleanup also contain VOCs. Unrestricted potential emissions from this process are 12.5 tpy. Covidien is proposing to limit the emissions from this process line to 9.0 tpy VOC as previously limited in MassDEP Approval #1-P-10-029.

Process line #6 (Sensors/EKG) produces tab electrodes and snap electrodes from solid UV gels, hydrogels, and wet gels on 14 machines in the EKG Sensor Rooms. Two additional pouch producing machines are also located in the sensor area. VOC emissions from the hydrogels are accounted for in Process line #4; however, potential

emissions of VOC emissions from the cleaning activities for this process line are 0.37 tpy VOC. EKG #8 is a Webtron 650 printing press located in this area, with potential emissions of 0.7 tpy VOC. Unrestricted potential VOC emissions from process line #6 are 1.07 tpy. Covidien is proposing to limit emissions from this line to 0.7 tpy VOC as previously limited in MassDEP Approval #1-P-10-029.

Process line #7 consists of the assembling of Defibrillator pads from parts made in other process lines at the facility. Emissions from the manufacturing of the Defibrillator pad parts are attributed to the process lines where the parts are constructed. VOC emissions from the assembling of Defibrillator pads are primarily due to cleaning solvents. Covidien is proposing to limit emissions from this line to 1.1 tpy VOC as previously limited in MassDEP Approval #1-P-10-029.

Process line #8 consists of three Mark Andy printing presses (#1, 2, 3). Each press consists of three printing stations and die cutting equipment. Two presses utilize flexo inks that are thinned prior to application, while the third utilizes a polyamide-based ink that is thinned prior to application. Covidien is proposing to limit emissions from this line to 1.7 tpy VOC as previously limited in MassDEP Approval #1-P-10-029.

Process line #9 consists of a parts washer that has been converted to a non-solvent based material.

Process line #11 consists of research and development operations which are being transferred to the Chicopee location for Oriskany Falls, New York. The equipment will be located in the former release coater room, near the "691" line, process line #2. Covidien proposes to limit the emissions to 1.0 tpy VOC.

Provisions of Approval

It is the opinion of MassDEP that the installation and operation of Line # 12 is consistent with Best Available Control Technology and good engineering practice. MassDEP hereby grants Final Approval for the operation described herein, pursuant to 310 CMR 7.02(3) and 310 CMR 7.02(5) of the Air Pollution Control Regulations, as contained in 310 CMR 7.00, subject to the following provisions:

Emission Limits and Operational Restrictions

1. Covidien shall comply with limits listed in Table 1 at all times:

Table 1			
Process Line	VOC Restriction	tons/month⁽¹⁾	tons/year⁽²⁾
Line #2 – 691 Line	Conductive Inks: ≤ 55% VOC by weight as applied Adhesive: 13% VOC by weight as applied UV inks: 1% VOC by weight as applied	7.2	12.0
Line #3 - Charts Printing	Oil-based inks: ≤ 52% VOC by weight as applied Flexo ink: 6% VOC by weight as applied UV inks: 1% VOC by weight as applied Specialty inks: 250 gals/year, No VOC restriction	3.0	4.0
Line #4 - 60's, 70's, 80's Lines	None	7.2	9.0
Line #6 – Sensors / EKG	None	0.5	0.7
Line #7 – Defibrillator	None	0.5	1.1
Line #8 – Mark Andy's #1,2,3	None	0.6	1.7
Line #9 - Maintenance Parts Washer	Non-solvent based system	0.0	0.0
Line #11 – R & D Activities	None	1.0	1.0
Line #12 – Wide Web Gel	None	2.5	3.1
Facility Total			32.6

Notes for Table 1

- (1) tons of VOC emitted includes any VOC emitted from the manufacturing performed in each processes, including cleaning materials
- (2) tons/year refers to tons of VOC emitted in any rolling twelve-month period

- 2. Covidien shall meet the following cleanup solution standards:
 - a. Cleanup solution shall be kept in covered containers during transport and storage;
 - b. Shop towels contaminated with cleanup solution shall be kept, when not in use, in covered containers; and
 - c. Covidien shall maintain records of cleanup solution VOC content and usage to demonstrate compliance with Provisions 6, 7, and 8 of this Approval.
- 3. Covidien shall not exceed 9.9 tons per year for any single Hazardous Air Pollutant (HAP) or 24.9 tons per year total HAPs.

Testing/Monitoring

4. Covidien shall, upon request of MassDEP, perform or have performed tests to demonstrate compliance.
5. Covidien shall establish and maintain a calendar month record of all coatings, inks or solvents used and the results of the reference test method (Method 24) or the manufacturer's formulation data used for determining VOC content of those coatings.

Recordkeeping

6. Covidien shall maintain daily records to demonstrate compliance with Table 1 limits which shall include, but are not limited to:
 - a. identity, quantity, formulation and density of coatings and inks used;
 - b. identity, quantity, formulation and density of any diluent(s) and clean-up solvents used;
 - c. solids content of any coating(s) used;
 - d. quantity of product processed.
7. Covidien shall generate monthly reports in-house that document compliance with all of the VOC emission limits specified within this approval.
8. All records shall be kept on site for a minimum of five (5) years from date of record and shall be made available to MassDEP upon request.

Reporting

9. MassDEP, must be notified by telephone or fax as soon as possible after the occurrence, but no later than one (1) business day after the occurrence, of any upsets or malfunctions to the facility equipment, air pollution control equipment, or monitoring equipment which result in an excess emission to the air and a condition of air pollution.
10. Covidien shall report within fifteen (15) days after the end of a calendar month if any emission limits are exceeded.
11. Covidien shall submit after the end of each calendar year (by January 31 of each year) the previous twelve (12) monthly reports, in accordance with the requirements of provision 6 of this Approval. At a minimum, the information shall include the calculated facility emissions of VOC for the month as well as the prior 11 months. An example of a format that is acceptable to MassDEP is the On-Site Record Keeping Form, which can be downloaded at <http://www.mass.gov/dep/air/approvals/reshome.htm>.

GENERAL CONDITIONS

1. In accordance with 310 CMR 7.12, Covidien shall accurately report on an annual basis, all information as required by the Source Registration/Emission statement form.
2. This approval may be suspended, modified, or revoked by MassDEP if, at anytime, MassDEP determines that any condition or part of this Approval is being violated.
3. The facility shall be constructed and operated in strict accordance with the application approved herein. Should there be any differences between the General Conditions or the aforementioned application, and this approval letter, this approval letter shall govern.
4. Covidien shall allow MassDEP personnel access to the site, buildings, and all pertinent records at all reasonable times for the purpose of making inspections and surveys, collecting samples, obtaining data, and reviewing records.
5. This approval pertains only to the air quality control aspect of the proposal and does not negate the responsibility of the owners or operators to comply with other applicable state, local, or federal laws and regulations.
6. MassDEP may revoke, in accordance with 310 CMR 7.02(3)(k), any plan approval if the actual construction has not begun within two (2) years from the date of issuance or if, during the construction, the construction is suspended for the period of one (1) year or more.
7. Should any nuisance condition(s), including but not limited to smoke, dust, odor or noise, occur, as the result of the operation of the facility, then Covidien shall immediately take appropriate steps to abate said nuisance condition(s).

MassDEP has determined that the filing of an Environmental Notification Form (“ENF”) with the Secretary of Environmental Affairs, for air quality purposes, was not required prior to this action by MassDEP. Notwithstanding this determination, the Massachusetts Environmental Policy Act, and regulation 301 CMR 11.00, section 11.04, provide certain “Fail-Safe” Provisions” which allow the Secretary to require the filing of an ENF and/or an Environmental Impact Report at a later time.

APPEAL PROCESS

This Final Approval is an action of MassDEP. If you are aggrieved by this action, you may request an adjudicatory hearing. A request for a hearing must be made in writing and postmarked within twenty-one (21) days of the date you received this document.

Under 310 CMR 1.01(6)(b), the request must state clearly and concisely the facts which are the grounds for the request and the relief sought. Additionally, the request must state why the Final Approval is not consistent with applicable laws and regulations.

The hearing request along with a valid check payable to the Commonwealth of Massachusetts in the amount of one hundred dollars (\$100) must be mailed to:

Commonwealth of Massachusetts
Department of Environmental Protection
P. O. Box 4062
Boston, MA 02211

The request will be dismissed if the filing fee is not paid, unless the appellant is exempt or granted a waiver as described below.

The filing fee is not required if the appellant is a city or town (or municipal agency), county, or district of the Commonwealth of Massachusetts, or a municipal housing authority.

MassDEP may waive the adjudicatory hearing-filing fee for a person who shows that paying the fee will create an undue financial hardship. A person seeking a waiver must file, together with the hearing request as provided above, an affidavit setting forth the facts believed to support the claim of undue financial hardship.

If there are any questions or comments regarding this Final Approval, please contact John Kirzec at (413) 755-2225 or the undersigned at (413) 755-2115.

Sincerely,

This final document copy is being provided to you electronically by the Department of Environmental Protection. A signed copy of this document is on file at the DEP office listed on the letterhead.

Marc Simpson
Permit Chief
Western Region

ecc: Yi Tian, DEP, Boston
Roberta Baker, WERO
Peter Czapienski, WERO