

**DEPARTMENT OF ENVIRONMENTAL QUALITY
AIR QUALITY DIVISION
ACTIVITY REPORT: Scheduled Inspection**

P030836668

FACILITY: Corium International Inc.		SRN / ID: P0308
LOCATION: 4558 50th St SE, GRAND RAPIDS		DISTRICT: Grand Rapids
CITY: GRAND RAPIDS		COUNTY: KENT
CONTACT: Laura Marsh , Environmental Health and Safety		ACTIVITY DATE: 09/20/2016
STAFF: David Morgan	COMPLIANCE STATUS: Compliance	SOURCE CLASS: MINOR
SUBJECT:		
RESOLVED COMPLAINTS:		

At 10:45 AM on September 20, 2016, Air Quality Division staff Dave Morgan conducted an unannounced scheduled inspection of Corium International Inc. located at 4524 and 4558 50th Street SE in Kentwood. The purpose of the inspection was to determine the facility's compliance with state and federal air pollution regulations. Accompanying staff on the inspection was Laura Marsh, Environmental Health and Safety Officer and Kevin Mulherin, Quality Validation Specialist.

FACILITY DESCRIPTION

Corium International Inc. is a manufacturer of drug delivery systems including transdermal systems. The facility consists of ingredient mixing, adhesive application, final product preparation and packaging. The facility also has research and development activities.

COMPLIANCE EVALUATION

The company has one main production line that emits volatile organic compounds (VOC) and which is exempt from air use permitting under Rule 290. This line consists of two mixing rooms and a web coating process. In the mixing rooms, solvents and other ingredients are mixed in 50 gallon (or less) vessels to create an adhesive that is applied to a polyethylene film substrate in an enclosed booth. Once the adhesive has been mixed, the vessel is transported to the web coater. In the web coater, the adhesive is pumped from the vessel onto a roller that then comes in contact with a spool of the film where the adhesive is applied. The solvents in the adhesive are then driven off the film in the drying oven at a temperature less than 200°F. The webcoater and oven are completely enclosed and all solvent laden air is exhausted through a thermal oxidizer.

According to manufacturer specifications, the thermal oxidizer is set to operate at a temperature of 1500°F in the combustion chamber. It is noted that the company conducted a stack test in March 2008 to verify that the destruction efficiency of the thermal oxidizer is at 98.28%

From July 2015 through August 2016, company records show that VOC emissions from the web coating process have not exceeded 140 pounds per month (in June 2015) which is well below the 500 pound per month VOC limit in Rule 290 for controlled emission units. It is noted that overall VOC emissions are typically less than 20 lbs per month.

Cleaning operations of mixing vessels is also an exempt process under Rule 290. The mixing vessels are cleaned using ethyl acetate and heptane in a closed loop where the solvent is pumped through the vessel and transferred back to a sealed drum for disposal. VOC emissions from this cleaning process are negligible because the company is recovering the cleaning solvent. Company records show 1,250 gallons of ethyl acetate and 1160 gallons of heptane were used for cleaning from September 2015 through August 2016. Again, due to solvent recovery, emissions are expected to be negligible.

There is a parts washer for manual cleaning operations. In this process the company pumps ethyl acetate solvent into the washer at the time of cleaning, immerses small tools or parts into the solvent which are brushed clean. Used solvent is pumped out of the parts washer into a waste drum when finished. No spraying is conducted. The unit has an air to vapor interface less than 10 ft², it is considered exempt from air use permitting under Rule 281(h).

Although the parts washer is exempt from air use permitting, the unit is subject to air pollution control Rule 707 for new cold cleaners. Since ethyl acetate is used which has a Reid vapor pressure of 3.27 psia (greater than 0.3 psia in the rule), the unit is to have a mechanically assisted cover, and a freeboard height to width ratio greater than 0.7. The lid is mechanically assisted using a foot pedal for operation and solvent levels are maintained to meet the freeboard ratio.

The company uses isopropyl alcohol (IPA) for sanitization purposes which can be considered exempt under Rule 290 as well. According to company records, no more than 112 gallons of IPA were used at the facility from September 2015 through August 2016 which equates to approximately 516 pounds of VOC emissions. This is below the applicable VOC limit in Rule 290.

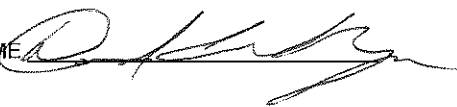
There are research and development activities at the facility which use a small amount of solvent which are exempt under Rule 283.

In 2013, the company installed a second coating line with an RTO at the 4524 building. This coating line was installed under the Rule 290 exemption, however, no production has occurred in this line since installation. It is noted that in 2015, the company conducted a destruction efficiency test of the new RTO while running trial material. The RTO destruction efficiency was determined to be 98.99% with an outlet concentration of 0.23 pounds of VOC per hour (see attached test summary).

There is one diesel-fired emergency generator located at the 4558 address with a rating of approximately 2.5 million Btu/hr (calculated from a rating of 230 kilowatts). In addition there is one diesel-fired emergency generator located at the 4524 address with a rating of 1.3 million Btu/hr (calculated from a rating of 100 kilowatts). Each generator is exempt from permitting under Rule 285(g) because they are rated less than 10 million Btu/hr.

SUMMARY

Corium International Inc. is in compliance with state and federal air pollution regulations evaluated.

NAME  DATE 9/20/16 SUPERVISOR 