

ENGINEERING EVALUATION
Micrus Endovascular, LLC
Application #25600
Plant #21487

BACKGROUND

Micrus Endovascular, LLC is requesting to change the permit conditions for the following equipment:

S-1 Wipe Cleaning Operation

Micrus Endovascular develops and manufactures medical devices for treatment of cerebral vascular diseases. The facility uses isopropyl alcohol (IPA) to wipe clean tables that are used for assembly of medical devices. A Permit to Operate was issued by BAAQMD on 12/17/12 via application 24725 with permit condition no. 25359, which limits the annual usage of IPA to 155 gallons and the permitted Precursor Organic Compound (POC) annual emissions to 1,013.7 pounds.

Micrus Endovascular submitted this application to increase IPA's permitted annual throughput to 220 gallons due to the increasing market demands in implantable medical devices.

EMISSION CALCULATIONS

Change of cleaning solvent results in increase of POC emissions. See Table 1 for POC emissions at 220 gallons per year.

Table 1. POC Emissions

Material	Net Usage (gal/yr)	Weight%	Density (lb/gal)	Hourly Emissions (lb/hr)	Daily Emissions (lb/day)	Annual Emissions	
						(lb/yr)	(TPY)
IPA	220	100%	6.54	0.69	5.53	1,438.8	0.719

PLANT CUMULATIVE INCREASE

There will be an emission increase of 0.212 tons of POC per year as a result of the proposed modification.

TOXICS RISK SCREENING ANALYSIS

As shown in Table 2, emissions of IPA from S-1 do not exceed District's trigger levels of Regulation 2, Rule 5 - New Source Review of Toxic Air Contaminants. Therefore, a Toxics Risk Screen is not required.

Table 2

Toxic Pollutant Emitted	Hourly Emission Rate (lb/hr)	Acute Trigger for Risk Screen (lb/hr)	Acute Triggered?	Annual Emission Rate (lb/yr)	Chronic Trigger for Risk Screen (lb/yr)	Chronic Triggered?
IPA	0.69	7.1	No	1,438.8	270,000	No

STATEMENT OF COMPLIANCE

S-1 is expected to comply with all applicable requirements specified in the application 24725 under which it

was permitted

Wipe cleaning operation S-1 is subject to and expected to comply with the storage and disposal requirements of Regulation 8-1-320 (*Surface Preparation; Clean-up; Coating, Ink, Paint Removal*), 321 (*Closed Containers*), and 322 (*Spray Equipment Clean-up Limitation*) and the recordkeeping requirements of Regulation 8-16-501 (*Solvent Records*) and Regulation 8-4-501 (*Recordkeeping Requirements*).

Per Regulation 8-4-116 (*Limited Exemption, Specific Surface Preparation and Cleaning Operations*), S-1 is exempt from Regulation 8-4-313 (*Surface Preparation Standards*), because S-1 is associated with medical device manufacturing operations.

S-1 is subject to and expected to comply with the 5 TPY VOC limit per Regulation 8-4-302.1 (*Solvents and Surface Coating Requirements*) since the permit condition will limit S-1 to 1438.8 lbs of POC.

The proposed project is considered to be ministerial under Regulation 2-1-311 (*Ministerial Projects*) and therefore is not subject to California Environmental Quality Act (CEQA) review. The engineering review for this project requires no more than the application of standard permit conditions and standard emission factors as described in the District's Permit Handbook Chapter 6.3 and therefore is not considered discretionary as defined by CEQA.

A Toxics Risk Screening Analysis is not required due to the emissions of IPA at the rates discussed above. TBACT does not apply to this project.

Pursuant to Regulation 2-2-304 (*PSD Requirement*), this project is not subject to PSD review because the facility is not a major facility emitting more than 100 TPY.

This application will not trigger BACT since the maximum daily emission of POC is less than 10 lb/day.

Offsets are not required since this facility does not emit more than 10 tons/yr of POC.

This facility is located within 1,000 feet from the nearest school (listed below) and therefore is subject to the public notification requirements of Regulation 2-1-412. A public notice was prepared and will be sent to the parents or guardians of children enrolled in any school within one-quarter mile of the source and to each address within a radius of 1,000 feet of the source.

Orchard School
921 Fox Lane
San Jose, CA 95131

PERMIT CONDITIONS

Condition 25359 will be modified to allow increasing IPA annual throughput to 220 gallons per year. Annual POC emissions will be increased to 1,438.8 pounds for S-1. The changes are shown in underline/strikeout format.

| Condition # ~~25359~~25670

Micrus Endovascular LLC
S-1 Wipe Cleaning Operation
| Application 25600 (August 2013), 24725 (August 2012)

1. The owner/operator of S-1 shall not exceed the following usage limits during any consecutive twelve-month period:
| Isopropyl alcohol ~~455~~220 Gallons
(Basis: Cumulative Increase)

2. The owner/operator may use an alternate solvent(s) other than the materials specified in Part 1 and/or usages in excess of those specified in Part 1, provided that the owner/operator can demonstrate that all of the following are satisfied:
 - a. Total POC emissions from S-1 do not exceed ~~4,013.71~~4,438.8 pounds in any consecutive twelve month period;
 - b. Total NPOC emissions from S-1 do not exceed ~~4,013.71~~4,438.8 pounds in any consecutive twelve month period;
 - c. The use of these materials does not increase toxic emissions above any risk screening trigger level of Table 2-5-1 in Regulation 2-5.
 - d. The use of these materials does not increase emissions of POC or NPOC above BACT trigger level (10 lb/day)(Basis: Cumulative Increase; Toxics)

3. To determine compliance with the above parts, the owner/operator shall maintain the following records and provide all of the data necessary to evaluate compliance with the above parts, including the following information:
 - a. Quantities of each type of solvent used at this source on a monthly basis.
 - b. If a material other than those specified in Part 1 is used, POC/NPOC and toxic component contents of each material used; and mass emission calculations to demonstrate compliance with Part 3, on a monthly basis;
 - c. Monthly usage and/or emission calculations shall be totaled for each consecutive twelve-month period.All records shall be retained on-site for two years, from the date of entry, and made available for inspection by District staff upon request. These recordkeeping requirements shall not replace the recordkeeping requirements contained in any applicable District Regulations.
(Basis: Cumulative Increase; Toxics)

End of Conditions

RECOMMENDATION

The District has reviewed the material contained in the permit application for the proposed project and has made a preliminary determination that the project is expected to comply with all applicable requirements of District, state, and federal air quality-related regulations. The preliminary recommendation is to issue an Authority to Construct for the equipment listed below. However, the proposed source will be located within 1000 feet of a school, which triggers the public notification requirements of District Regulation 2-1-412.6. After the comments are received and reviewed, the District will make a final determination on the permit.

I recommend that the District initiate a public notice and consider any comments received prior to taking any final action on issuance of a Permit to Operate to **Micrus Endovascular, LLC** for the following source:

S-1 Wipe Cleaning Operation

Application #25600

Micrus Endovascular, LLC

Plant #21487

Janice Wu
Temporary Air Quality Engineer
Engineering Division

Date

Scott Owen
Supervising Air Quality Engineer
Engineering Division

Date

SAO:JW:jw