

ENGINEERING EVALUATION
Micrus Endovascular, LLC
Application #24725
Plant #21487

BACKGROUND

Micrus Endovascular, LLC has applied for a Permit to Operate for the following operation at 821Fox Lane, San Jose, CA 95131

S-1 Wipe Cleaning Operation

S-1 has been in operation since 2/1/06 without a Permit to Operate issued by BAAQMD. Late fee and back fee are assessed.

Micrus Endovascular LLC develops and manufactures medical devices for treatment of cerebral vascular diseases. The facility uses 155 gallons of isopropyl alcohol (IPA) annually to wipe clean tables that are used for assembly of medical devices.

EMISSION CALCULATIONS

Basis:

- Annual Usage: 155 gallons of 100% IPA
- Operating Schedule: 8 hours/day, 5 days/week, 52 weeks/year.
- Approximately 260 operation days per year
- Any organic solvents used for wipe cleaning are assumed to be 100 percent volatile and emitted into the atmosphere per District's policy.

Annual Average Emissions:

Annual emissions are calculated by multiplying the annual gross solvent usage by the density of the organic solvent.

Daily Emissions:

Based on the operating schedule, average daily emissions are calculated to establish whether a source triggers the requirement for BACT (10 lb/highest day total source emissions for any class of pollutants). See Table 1.

Table 1 Emission of S-1

Solvent	Net Usage (gal/yr)	Concentration	Density (lb/gal)	Hourly Emissions (lb/hr)	Daily Emissions (lb/day)	Annual Emissions	
						(lb/yr)	(TPY)
IPA (POC)*	155	100%	6.54	0.49	3.90	1013.7	0.507

* POC = Precursor Organic Compound (NPOC = Non-Precursor Organic Compound)

PLANT CUMULATIVE INCREASE SINCE 4/5/1991

To allow flexibility of solvent used for S-1, the applicant will be allowed to emit 0.507 TPY of NPOC. Table 2 summarizes the cumulative increase in criteria pollutant emissions that will result at Plant 21487 from the operation of S-1.

Table 2 Plant Cumulative Increase

Pollutants	Current Emissions (TPY)	New Emissions (TPY)	New Total Emissions (TPY)
POC	0	0.507	0.507
NPOC	0	0.507	0.507

OFFSETS

Offsets must be provided for any new or modified source at a facility that emits more than 10 tons/yr of POC or NOx per Regulation 2-2-302. Table 2 indicates that S-1 does not warrant any offsets for the emission of criteria pollutants.

TOXIC SCREENING ANALYSIS

Table 3

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	0.49	7.1	No	1,013.7	270,000	No

As shown in Table 3, emissions of toxic air contaminants from S-1 do not exceed any District trigger level of Regulation 2-5, and a Toxics Risk Screen is therefore not required.

BEST AVAILABLE CONTROL TECHNOLOGY (BACT)

In accordance with Regulation 2, Rule 2, Section 301, BACT is triggered for any new or modified source with the potential to emit 10 pounds or more per highest day of POC, NPOC, NOx, CO, SO₂ or PM₁₀. As shown in Table 2, the POC daily emission does not exceed 10 pounds. Therefore, S-1 does not trigger the BACT requirements Regulation 2-2-301.1.

STATEMENT OF COMPLIANCE

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 1013.7 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.

Offsets, NSPS, and NESHAPS are not triggered.

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 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 1000 feet of the source.

Orchard School
921 Fox Lane
San Jose, CA 95131

CONDITIONS

Condition # 25359

Micrus Endovascular LLC
S-1 Wipe Cleaning Operation
Application 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 155 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 1,013.7 pounds in any consecutive twelve month period;
 - b. Total NPOC emissions from S-1 do not exceed 1,013.7 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 a Permit to Operate 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

Douglas Hall
Supervising Air Quality Engineer
Engineering Division

DWH:JW:jw