

**DRAFT**  
**ENGINEERING EVALUATION**  
**Conor Medsystems**  
 Application #16681- Plant #18148

**1003 Hamilton Ct.**  
**Menlo Park, CA 94025**

**I. BACKGROUND**

Conor Medsystems submitted this application for an Authority to Construct/Permit to Operate for the following equipment:

**S-4 Wipe Cleaning Operation**

This wipe cleaning operation is used to wipe down work surfaces and equipment in a clean manufacturing environment to maintain cleanliness requirements for medical device manufacture. Source S-4 will use approximately 400 gallons of isopropyl alcohol, EMD Chemical, Inc. PX1830 per year.

**II. EMISSION CALCULATIONS**

S-4 POC emissions

Basis:

- 400 gallons/yr isopropyl alcohol
- POC content of 6.55 lb/gal
- Operating time of 8 hr/day, 5 day/wk, 50 wk/yr

Annual Emissions

POC emissions: (400 gal/yr)(6.55 lb/gal POC) = 2620 lb/yr = **1.310 tpy POC**

Daily Emissions

(400 gal/yr)(6.55 lb/gal POC)/[(5 days/wk)(50wk/yr)] = **10.48 lb/day POC**

Hourly Emissions

(400 gal/yr)(6.55 lb/gal POC)/[(8hr/day)(5 days/wk)(50wk/yr)] = **1.31 lb/hr POC**

**III. PLANT CUMULATIVE INCREASE**

	<u>Current</u> <u>(post 4/5/1991)</u>	<u>New This</u> <u>Application</u>	<u>New Total</u>
	<u>Ton/yr</u>	<u>Ton/yr</u>	<u>Tons/yr</u>
<b>POC =</b>	0.032	1.310	1.342
<b>NO<sub>x</sub> =</b>	0.600	-	0.600
<b>SO<sub>2</sub> =</b>	0.016	-	0.016
<b>PM10 =</b>	0.011	-	0.011
<b>NPOC =</b>	0.000	-	0.000
<b>CO =</b>	0.071	-	0.071

**IV. TOXIC SCREENING ANALYSIS**

The EMD Chemical, Inc. PX1830 contains 100% by weight isopropyl alcohol (IPA).

<b>Toxic Pollutant Emitted</b>	<b>Hourly Emission Rate (lb/hr)</b>	<b>Acute Trigger for Risk Screen (lb/hr)</b>	<b>Acute Triggered?</b>	<b>Annual Emission Rate (lb/yr)</b>	<b>Chronic Trigger for Risk Screen (lb/yr)</b>	<b>Chronic Triggered?</b>
IPA	1.31	7.1	no	2,620	270,000	no

As shown in the table above, a health risk screen is not triggered.

**V. BEST AVAILABLE CONTROL TECHNOLOGY**

This application requires BACT since the POC emissions from source S-4 are more than the 10 pounds per highest day threshold limit per Regulation 2-2-301. BACT(1) is not cost-effective for this application because the wipe cleaning operation maximally emits 1.310 tons POC/year and runs 8 hr/day, 5 day/wk, 50 wk/yr. At this low level of emissions, no air flow rate to a thermal oxidizer would be cost-effective, as can be seen by the cost-effectiveness curve in Appendix C2 of the BACT/TBACT Workbook. Source S-4 uses BACT(2) according to BACT/TBACT Handbook Section Document 179B.1, dated 2/4/93, which is compliance with minimizing the use of solvents; using the lowest practical vapor pressure solvents; and using a controlled flow solvent dispenser; and keeping all cloths/papers and solvents not in active use in closed containers (per supplemental information from applicant, provided 10/29/2007).

**VI. OFFSETS**

Offsets are not required since the facility's POC emissions of are less than 10 ton/yr per Regulation 2-2-302.

**VII. STATEMENT OF COMPLIANCE**

Wipe cleaning operation S-4 is subject to and expected to comply with the recordkeeping requirements of Regulation 8-16-501 as these requirements will be included in the permit conditions.

S-4 is subject to and expected to comply with the 5 tpy VOC limit per Regulation 8-4-302.1 since the permit condition will limit S-4 to 1.310 tpy POC and no NPOC.

S-4 is subject to and expected to comply with the storage/container requirements of Regulation 8-1-321 and Regulation 8-4-312 as the solvent is dispensed from squeeze bottles and spent wipes are stored in closed containers. This ensures that solvent does not evaporate into the air unless it is dispensed.

Per Regulation 8-4-116, Limited Exemption, Specific Surface Preparation and Cleaning Operations, S-4 is exempt from Regulation 8-4-313, Surface Preparation Standards, because S-4 is used for medical device or pharmaceutical manufacturing operations.

The proposed project is considered to be ministerial under Regulation 2-1-311 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 discretionary as defined by CEQA.

This project is less than 1,000 ft from the nearest public school and is therefore subject to the public notification requirements of Regulation 2-1-412.

PSD, NSPS, and NESHAPS are not triggered.

## VIII. CONDITIONS

Condition # 23793

Conor Medsystems, Plant No. 18148  
Application 16681

### S-4 Wipe Cleaning Operation

1) The owner/operator of S-4 shall ensure that total amount of EMD Chemical, Inc. PX1830 isopropyl alcohol used for wipe cleaning at this source does not exceed 400 gallons in any consecutive twelve-month period.

[Basis: Cumulative Increase]

2) Cleanup solvents other than the material specified in Part 1, and/or usage in excess of that specified in Part 1, may be used at S-4, provided that the owner/operator can demonstrate that both the following are satisfied:

- a. Total POC emissions from S-4 do not exceed 2,620 pounds in any consecutive twelve-month period.
- b. The usage of these materials does not increase toxic emissions above any chronic trigger level listed in Table 2-5-1 in District Regulation 2-5.

[Basis: Cumulative Increase, Toxics]

3) The owner/operator of S-4 shall minimize the use of solvents, use controlled flow solvent dispensers (e.g. squeeze bottles), and keep all cloths/papers and solvents not in active use in closed containers.

[Basis: Cumulative Increase]

4) To determine compliance with the above conditions, the owner/operator shall maintain the following records and provide all of the data necessary to evaluate compliance with the above conditions, including, but not necessarily limited to the following information:

- a. Type and monthly usage of all POC containing materials used;
- b. If a material other than the one specified in Part 1 is used or a material specified in Part 1 is used in excess of the limit in Part 1, POC and toxic component contents of each material used; and mass emission calculations to demonstrate compliance with Part 2, on a monthly basis;
- c. Monthly usage and/or emission calculations shall be totaled for each consecutive twelve-month period.

[Basis: Cumulative Increase]

**IX. RECOMMENDATION**

Issue a conditional Permit to Operate for the following equipment:

**S-4 Wipe Cleaning Operation**

*Kathleen Truesdell*  
*Air Quality Engineer I*  
*Engineering Division*

*date: 11/8/07*