

**DRAFT
ENGINEERING EVALUATION
Acclarent, Inc.
Application #21031
Plant #19870**

I. BACKGROUND

Acclarent, Inc. has applied for an Authority to Construct and/or Permit to Operate for the following equipment at their 1525B O'Brien Drive, Menlo Park, CA 94025 facility:

S-1 Wipe Cleaning Operation

Acclarent, Inc. is a facility that conducts research and development of tools used in sinus surgery. The facility also assembles and packages some of the sinus surgery tools for distribution. The facility will use the wipe cleaning operation to clean work surfaces and to clean the medical devices before final packaging of sinus surgery tools, utilizing disposable wipes. Annually, source S-1 will utilize approximately 42 gallons of 70% IPA (isopropyl alcohol) and 36 gallons of 99% IPA.

II. EMISSION CALCULATIONS

Basis:

- Operating Schedule: 10 hours/day, 5 days/week, 52 weeks/year.
- Assumptions: Any organic solvents used at S-1 are 100% volatile and emitted into the atmosphere.

Annual Average Emissions:

Annual emissions are calculated based on the above basis for operating schedule. See Table 1.

Daily Emissions:

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

Solvent	Net Usage (gal/yr)	Density (lb/gal)	Hourly Emissions (lb/hr)	Daily Emissions (lb/day)	Annual Emissions	
					(lb/yr)	(TPY)
70% IPA (POC)*	42.1	6.55	0.106	1.06	275.9	0.1380
99% IPA (POC)*	35.9	6.55	0.090	0.90	235.1	0.1175

* POC = Precursor Organic Compound

III. PLANT CUMULATIVE INCREASE SINCE 4/5/1991

Acclarent, Inc. at "1525B O'Brien Drive, Menlo Park, CA 94025" is a new facility. Therefore, the District's database does not contain information on existing emissions at the plant. Table 2 summarizes the cumulative increase in criteria pollutant emissions that will result at Plant 19870 from the operation of S-1.

Table 2

Pollutants	Current Emissions (TPY)	New Emissions (TPY)	New Total Emissions (TPY)
POC	0.0000	0.2555	0.2555
NOx	0.0000	0.0000	0.0000
SO ₂	0.0000	0.0000	0.0000
CO	0.0000	0.0000	0.0000
PM ₁₀	0.0000	0.0000	0.0000
NPOC	0.0000	0.0000	0.0000

IV. 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. Acclarent, Inc. at “1525B O’Brien Drive, Menlo Park, CA 94025” is a new facility. According to Table 2 that summarizes the increase in criteria pollutant emissions that will result from the operation of S-1, offsets are not required because the facility will emit less than 10 tons per year of POC.

V. 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	0.197	7.1	No	511.0	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 not required.

VI. 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. With the highest daily POC emissions not in excess of 10 pounds, S-1 Wipe Cleaning Operation does not trigger the BACT requirements Regulation 2-2-301.1.

VII. 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 used for surface preparation associated with research and development 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 511 lb 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 less than 1,000 feet from the nearest school and therefore is subject to the public notification requirements of Regulation 2-1-412 (*Public Notice, Schools*). A public notice will be prepared and sent to all addresses within 1000 feet of the diesel generator set and parents and guardians of students of the following schools:

Costano Elementary School
2695 Fordham Street
East Palo Alto, CA 94303-1207

San Francisco 49ers Academy
2695 Fordham Street
East Palo Alto, CA 94303-1207

Cesar Chavez Academy
2450 Ralmar Avenue
East Palo Alto, CA 94303-1040

Green Oaks Academy
2450 Ralmar Avenue
East Palo Alto, CA 94303-1040

VIII. CONDITIONS

Condition #24484

Acclarent, Inc.
S-1 Wipe Cleaning Operation
Application 21031 (August 2009)

1. The owner/operator of S-1 shall not exceed the following usage limits during any consecutive twelve-month period:

70% IPA (Isopropyl alcohol)	42 Gallons
99% IPA (Isopropyl alcohol)	36 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 511 pounds in any consecutive twelve month period; and
 - b. 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.
 (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 2, 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

IX. RECOMMENDATION

Issue Acclarent, Inc. an Authority to Construct and/or Permit to Operate for the following equipment:

S-1 Wipe Cleaning Operation

Kevin Oei
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DATE: 12/22/09