

DRAFT
ENGINEERING EVALUATION REPORT
ACCLARENT, INC.
PLANT NUMBER 19870
APPLICATION NUMBER 25118

1525B O'Brien Drive
Menlo Park, CA 94025

BACKGROUND

Acclarent, Inc. has been operating a facility in Menlo Park, where medical devices (tools used in sinus surgery) are assembled and packed. Isopropyl alcohol (70%) is used to wipe clean work stations, etc., and 99% isopropyl alcohol is used for cleaning devices. Usage of isopropyl alcohol for wipe cleaning is limited by permit condition ID# 24484. The applicant has requested for an increase in the usage of 99% alcohol from the current limit of 75 gallons to 125 gallons per year.

The application covers the following source:

S-1 Wipe Cleaning Operation.

EMISSION CALCULATIONS

VOC emissions are calculated on the basis of the material usage, and the VOC content of the materials.

Isopropyl alcohol (99%) usage = 75 gallons/yr (current);
125 gallons/yr (proposed)

Isopropyl alcohol (70%) usage = 250 gallons/yr (current);
No change is proposed

Isopropyl alcohol density = 6.53 lb/gallon

$$\begin{aligned} \text{POC emissions increase} &= (125-75 \text{ gallons/yr}) (99\%) (6.53 \text{ lb/gallon}) \\ &= \mathbf{323.24 \text{ lb/yr}} \\ &= \mathbf{0.162 \text{ tpy}} \end{aligned}$$

$$\begin{aligned} \text{Maximum daily POC emissions} &= [(250 \text{ gallons/yr}) (70\%) \\ &\quad + (125 \text{ gallon/yr}) (99\%)] (6.53 \text{ lb/gallon}) / \\ &\quad (260 \text{ days/yr}) \\ &= \mathbf{7.5 \text{ lb/day}} \end{aligned}$$

PLANT CUMULATIVE INCREASE

POC = 0.162 tpy

TOXICS EMISSIONS AND RISK SCREEN ANALYSIS

Toxic emissions are calculated on the basis of the material's toxic content.

$$\begin{aligned} \text{Isopropyl alcohol} &= [(250 \text{ gallons/yr}) (70\%) \\ &\quad + (125 \text{ gallon/yr}) (99\%)] (6.53 \text{ lb/gallon}) \\ &= \mathbf{1950.84 \text{ lb/yr}} \text{ (TTL = } 2.7\text{E}+05 \text{ lb/yr)} \\ &= \mathbf{7.5 \text{ lb/day}} \end{aligned}$$

= 0.75 lb/hr @10 hrs/day (TTL = 7.1 lb/hr)

Emissions of isopropyl alcohol are below the toxic trigger limits given in the Table 2-5-1 of Regulation 2-5, and therefore a toxic risk screening is not required.

STATEMENT OF COMPLIANCE

On the basis of the information submitted, the source (S-1) is subject to and will comply with the requirements of Regulation 8, Rule 4 (Section 8-4-302). POC emissions are less than 5 tpy. The sources are exempt from the requirements of Regulation 8-4-313 per Section 8-4-116.

8-4-302 Solvents and Surface Coating Requirements: A person shall not use solvents or apply surface coatings unless one or more of the following requirements are satisfied:

302.1 A person shall not emit more than 4,533 kg (5 tons) of volatile organic compounds (VOC) from any source during any calendar year; or

302.2 Emissions are controlled by an approved emission control system with an overall abatement efficiency of 85% on a mass basis. If reduction is achieved by incineration, at least 90% by weight of the organic compound emissions shall be oxidized to carbon dioxide; or

302.3 The coating operation uses a coating with a VOC content less than or equal to 420 grams per liter (3.5 lb/gal) of coating as applied.

(Amended 3/17/82; 6/1/94; 5/15/96; 10/16/02)

8-4-116 Limited Exemption, Specific Surface Preparation and Cleaning Operations:

The surface preparation standards in Section 8-4-313 shall not apply to (i) the surface preparation of electrical and electronic components, precision optics, or numismatic dies; (ii) stripping of cured inks, coatings and adhesives or cleaning of resin, coating, ink and adhesive mixing, molding and application equipment; or, (iii) surface preparation associated with research and development operations; medical device or pharmaceutical manufacturing operations; performance testing to determine coating, adhesive or ink performance; or testing for quality control or quality assurance purposes.

The project does not trigger CEQA review since it is considered ministerial under the District's CEQA Regulation 2-1-311. Permit evaluation is done as per standard procedures give in Permit Handbook Chapter 6.3.

A toxic risk screening analysis is not required because emissions of toxic compounds are not expected to exceed the toxic trigger levels given in the Table 2-5-1 of Regulation 2-5. TBACT does not apply.

Public notification requirements of Regulation 2-1-412 are triggered because there is a school located within 1000 feet of the source.

BACT requirements of regulation 2-2-301 are not triggered for POC emissions < 10 lb/day from the source.

Offset requirements of Regulation 2-2-302 are not triggered because facility wide POC emissions are less than 10 tons/yr.

PSD, NSPS, and NESHAPS do not apply.

PERMIT CONDITIONS

Permit condition ID# 24484 is revised by increasing the 99% IPA limit.

Condition # 24484

S-1, Wipe Cleaning Operation

(Revision 1: Application 22541; [Revision 2: A# 25118](#))

1. The owner/operator of S-1 shall not exceed the following usage limits during any consecutive twelve-month period:
70% Isopropyl alcohol 250 Gallons
99% Isopropyl alcohol ~~7125~~ [1950.84](#) 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 ~~1637.5~~ [1950.84](#) pounds in any consecutive twelve month period;
 - 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)

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 District initiate a public notice and consider any comments received prior to taking any final action on issuance of an Authority to Construct for the following source:

S-1 Wipe Cleaning Operation

BY: _____
Dharam Singh, AQE