

DRAFT
ENGINEERING EVALUATION REPORT
Intersect ENT
PLANT NUMBER 21321
APPLICATION NUMBER 24481

1555 Adams Drive
Menlo Park, CA 94025

BACKGROUND

On behalf of Intersect ENT, Green Environment, Inc. has submitted an application to install a medical device coating system to coat "stent" with a formulated proprietary coating, and facility wide solvent cleaning operation. The coating is consisted of a polymer, a drug, and acetone as a carrier solvent. After coating, acetone flashes off and the "stent" is dried by blowing nitrogen over it. Acetone is also used for cleaning metal holder and stirring rods at the coating system. Isopropyl alcohol is used for facility wide cleaning operation. However, Part 2 of the permit condition will allow the facility to change formulations and/or materials provided that emissions do-not exceed both toxic trigger levels given in Table 2-5-1 of Regulation 2-5 and the permitted emission levels. No new public notification is required if Part 2 is satisfied.

The application covers the following sources:

- S-1 Medical Device Coating System (7 Benchtop units), SONO TEK Corp., Medi-Coat DES 1000, and solvent cleaning.**
- S-2 Wipe Cleaning (facility wide).**

EMISSION CALCULATIONS

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

S-1:

- a. Proprietary Coating = 150 gallons/yr, 0.5 gallon/day; VOC content = 98.5% by volume; Density of solvent (acetone) = 6.6 lb/gallon
- b. Acetone = 100 gallons/yr, 0.5 gallon/day; Density = 6.6 lb/gallon

$$\begin{aligned} \text{NPOC emissions} &= [(150 \text{ gallons/yr})(98.5\%)+(100 \text{ gallons/yr})](6.6 \text{ lb/gallon}) \\ &= 1635.15 \text{ lb/yr} \\ &= 0.818 \text{ tpy} \end{aligned}$$

$$\begin{aligned} \text{Maximum daily NPOC emissions} &= [(0.5 \text{ gallon/day})(98.5\%)+(0.5 \text{ gallon/day})] \\ &\quad (6.6 \text{ lb/gallon}) \\ &= 6.55 \text{ lb/day} \end{aligned}$$

S-2:

- a. Isopropyl alcohol usage = 110 gallons/yr, 0.5 gallon/day; Density = 6.53 lb/gallon

$$\begin{aligned} \text{POC emissions} &= (110 \text{ gallons/yr})(6.53 \text{ lb/gallon}) \\ &= 718.3 \text{ lb/yr} \\ &= 0.359 \text{ tpy} \end{aligned}$$

$$\begin{aligned} \text{Maximum daily POC emissions} &= (0.5 \text{ gallon/day})(6.53 \text{ lb/gallon}) \\ &= 3.265 \text{ lb/day} \end{aligned}$$

PLANT CUMULATIVE INCREASE

POC = 0.359 tpy
NPOC = 0.818 tpy

TOXICS EMISSIONS AND RISK SCREEN ANALYSIS

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

Isopropyl alcohol = (110 gallons/yr) (6.53 lb/gallon)
= **718.3 lb/yr** (TTL = 2.7E+05 lb/yr)
= **3.265 lb/day**
= **0.408 lb/hr @8 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 and NPOC 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 Chapters 6.3 & 11.9.

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 sources. However, Part 2 of the permit condition will allow the facility to change formulations and/or materials provided that emissions do-not exceed both toxic trigger levels given in Table 2-5-1 of Regulation 2-5 and the permitted emission levels. No new public notification is required if Part 2 is satisfied.

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

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

S-1 and S-2

1. The owner/operator shall not exceed the following usage limits at the sources during any consecutive 12-month period.

S-1:

- a. Proprietary Coating = 150 gallons
- b. Acetone = 100 gallons

S-2:

- a. Isopropyl alcohol = 110 gallons
(Basis: Cumulative Increase)
2. The owner/operator may use alternate coatings or cleanup solvents other than 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 and S-2 in Part 1 do not exceed 718 pounds in any consecutive 12-month period;
 - b. Total NPOC emissions from S-1 and S-2 in Part 1 do not exceed 1635 pounds in any consecutive 12-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.
(Basis: Cumulative Increase; Toxics)
3. To determine compliance with above parts, the owner/operator shall maintain the following records and provide all the data necessary to evaluate compliance with the above parts, including the following information:
 - a. Quantities of each type of coating and cleanup

- solvent used at each source in Part 1 on a monthly basis;
- b. If 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 12-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)

RECOMMENDATIONS

It is recommended that Intersect ENT be issued Permits to Operate (waive A/C) the sources, S-1 and S-2, described in the background section of this report.

EXEMPTION: None

BY: _____
Dharam Singh, AQE