



Florida Department Of Environmental Protection

Northeast District
8800 Baymeadows Way West, Suite 100
Jacksonville, Florida 32256

Ron DeSantis
Governor

Jeanette Nuñez
Lt. Governor

Shawn Hamilton
Secretary

January 10, 2022

Sent via email: kstamler@nicopure.com

Pure Laboratories, LLC (formerly Nicopure Labs, LLC)
Mr. Kenneth Stamler, Vice President of Shipping and Logistics
5909 NW 18th Drive
Gainesville, Florida 32653

SUBJECT: Florida Department of Environmental Protection v. Pure Laboratories, LLC
OGC File No. 21-0973
DEP Facility ID: FLD 054 061 049

Dear Mr. Stamler:

Enclosed is a copy of the executed Consent Order to resolve Case Number 21-0973.

The effective date of this Order is January 10, 2022, and all time frames will be referenced from this date.

As a reminder, a Consent Order is a binding legal document and was voluntarily entered into by both parties.

Should you have any questions concerning the Consent Order, please contact Bonnie Bradshaw at (904) 256-1638, or via e-mail at Bonnie.Bradshaw@FloridaDEP.gov. Your continued cooperation in the matter is appreciated.

Sincerely,

A handwritten signature in blue ink that reads "James R. Maher".

James R. Maher, PE
Assistant Director

Enclosure: Executed Consent Order

cc: FDEP-OGC: Lea Crandall, Agency Clerk
FDEP-NED: Arlene Wilkinson, DEP_NED



FLORIDA DEPARTMENT OF Environmental Protection

Northeast District
8800 Baymeadows Way West, Suite 100
Jacksonville, Florida 32256

Ron DeSantis
Governor

Jeanette Nuñez
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Shawn Hamilton
Secretary

January 6, 2022

Sent electronically to: kstamler@nicopure.com

Pure Laboratories, LLC (formerly Nicopure Labs, LLC)
Mr. Kenneth Stamler, Vice President of Shipping and Logistics
5909 NW 18th Drive
Gainesville, Florida 32653

SUBJECT: Department of Environmental Protection v. Pure Laboratories, LLC
OGC File No.: 21-0973
EPA/DEP ID: FLD 054 061 049

Dear Mr. Stamler:

The State of Florida Department of Environmental Protection ("Department") finds that Pure Laboratories, LLC ("Respondent") did not mark one satellite and two central hazardous waste accumulation containers with an indication of the hazards of the contents, did not conduct weekly inspections of two hazardous waste central accumulation areas, did not label two containers as "hazardous waste," did not label two containers of hazardous waste with the accumulation start date, had a small quantity of hazardous waste accumulating in a spill pallet under a hazardous waste accumulation container, did not have all the required emergency equipment in two areas, did not submit a Quick Reference Guide to emergency responders when the Contingency Plan was amended and did not amend the Contingency Plan when the list of emergency coordinators changed. This is in violation of the rules and statutes cited in the attached Warning Letter (WL21-179). Before sending this letter, the Department requested that the Respondent undertake certain actions to resolve the violations. These actions have since been completed. However, due to the nature of the violations, the Respondent remains subject to civil penalties. The Respondent is also responsible for costs incurred by the Department during the investigation of this matter.

The Department's Offer

Based on the violations described above, the Department is seeking \$5,321.00 in civil penalties and \$500.00 for costs and expenses the Department has incurred in investigating this matter, which amounts to a total of \$5,821.00. The civil penalty in this matter includes one violation of \$2,000.00 or more.

Respondent's Acceptance

If you wish to accept this offer and fully resolve the enforcement matter pending against the Respondent, please sign this letter and return it to the Department at 8800 Baymeadows Way West, Suite 100, Jacksonville, Florida, 32256, by January 28, 2022. The Department will then countersign it and file it with a designated clerk of the Department.

Once the document is filed with the designated clerk, it will constitute a final order of the Department pursuant to Section 120.52(7), Florida Statutes (F.S.), and will be effective unless a request for an administrative hearing is filed by a third party in accordance with Chapter 120, F.S., and the attached Notice of Rights.

By accepting this offer you, Mr. Stamler:

- (1) certify that you are authorized and empowered to negotiate, enter into, and accept the terms of this offer in the name and on behalf of Respondent;
- (2) acknowledge and waive Respondent's right to an administrative hearing pursuant to Sections 120.569 and 120.57, F.S., on the terms of this offer, once final; and
- (3) acknowledge and waive Respondent's right to an appeal pursuant to Section 120.68, F.S.

The Department acknowledges that the Respondent's acceptance of this offer does not constitute an admission of liability for the violation(s) referenced above.

Respondent's Performance

After signing and returning this document to the Department:

- (1) Respondent must pay \$5,821.00, in full, within 60 days from the execution date of this Order.
- (2) Respondent shall make all payments required by this Order by cashier's check, money order or on-line payment. Cashier's check or money order shall be made payable to the "Department of Environmental Protection" and shall include both the OGC number assigned to this Order and the notation "Water Quality Assurance Trust Fund." Payment shall be sent to the Department of Environmental Protection, 8800 Baymeadows Way West, Suite 100, Jacksonville, Florida, 32256. Online payments by e-check can be made by going to the DEP Business Portal at: <http://www.fldepportal.com/go/pay/>. It will take a number of days after this order is final and effective, by filing with the Clerk of the Department, before ability to make online payment is available.

The Department may enforce the terms of this document, once final, and seek to collect monies owed pursuant to Sections 120.69 and 403.121, F.S.

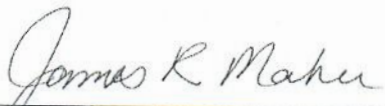
Until clerked by the Department, this letter is only a settlement offer and not a final agency action. Consequently, neither the Respondent nor any other party may request an administrative hearing to contest this letter pursuant to Chapter 120, F.S. Once this letter is clerked and becomes a final order of the Department, as explained above, the attached Notice of Rights will apply to parties, other than the Respondent, whose interests will be substantially affected.

Electronic signatures or other versions of the parties' signatures, such as .pdf or facsimile, shall be valid and have the same force and effect as originals. No modifications of the terms of this Order will be effective until reduced to writing, executed by both Respondent and the Department, and filed with the clerk of the Department.

Please be aware that if the Respondent declines to respond to the Department's offer, the Department will assume that the Respondent is not interested in resolving the matter and will proceed accordingly.

If you have any questions, contact Bonnie Bradshaw at (904) 256-1638, or via e-mail at Bonnie.Bradshaw@FloridaDEP.gov.

Sincerely,



James R. Maher, PE
Assistant Director

FOR THE RESPONDENT:

I, Ken Stamler, HEREBY ACCEPT THE TERMS OF THE
SETTLEMENT OFFER IDENTIFIED ABOVE.

By:  Date: 1/10/2022
[Signature]

Title: VP of Warehouse Operations & Logistics, Pure Laboratories, LLC
[Type or Print]

FOR DEPARTMENT USE ONLY

DONE AND ORDERED this 10th day of January 2022, in Duval
County, Florida.

STATE OF FLORIDA DEPARTMENT
OF ENVIRONMENTAL PROTECTION



Gregory J. Strong

J District Director

Filed, on this date, pursuant to section 120.52, F.S., with the designated Department Clerk,
receipt of which is hereby acknowledged.



Clerk

January 10, 2022

Date

Attachments: Notice of Rights
 Warning Letter WL21-179

Final clerked copy furnished to:

Lea Crandall, Agency Clerk (lea.crandall@floridadep.gov)

Arlene Wilkinson, FDEP NED (arlene.wilkinson@floridadep.gov)

NOTICE OF RIGHTS

Persons who are not parties to this Order, but whose substantial interests are affected by it, have a right to petition for an administrative hearing under Sections 120.569 and 120.57, Florida Statutes. Because the administrative hearing process is designed to formulate final agency action, the filing of a petition concerning this Order means that the Department's final action may be different from the position it has taken in the Order.

The petition for administrative hearing must contain all of the following information:

- a) The OGC Number assigned to this Order;
- b) The name, address, and telephone number of each petitioner; the name, address, and telephone number of the petitioner's representative, if any, which shall be the address for service purposes during the course of the proceeding;
- c) An explanation of how the petitioner's substantial interests will be affected by the Order;
- d) A statement of when and how the petitioner received notice of the Order;
- e) Either a statement of all material facts disputed by the petitioner or a statement that the petitioner does not dispute any material facts;
- f) A statement of the specific facts the petitioner contends warrant reversal or modification of the Order;
- g) A statement of the rules or statutes the petitioner contends require reversal or modification of the Order; and
- h) A statement of the relief sought by the petitioner, stating precisely the action petitioner wishes the Department to take with respect to the Order.

The petition must be filed (received) at the Department's Office of General Counsel, 3900 Commonwealth Boulevard, MS# 35, Tallahassee, Florida 32399-3000 within 21 days of receipt of this notice. A copy of the petition must also be mailed at the time of filing to the District Office at the address indicated above. Failure to file a petition within the 21-day period constitutes a person's waiver of the right to request an administrative hearing and to participate as a party to this proceeding under Sections 120.569 and 120.57, Florida Statutes. Mediation under Section 120.573, Florida Statutes, is not available in this proceeding.



FLORIDA DEPARTMENT OF Environmental Protection

Northeast District
8800 Baymeadows Way West, Suite 100
Jacksonville, Florida 32256

Ron DeSantis
Governor

Jeanette Nuñez
Lt. Governor

Shawn Hamilton
Interim Secretary

September 3, 2021

Sent electronically to: bvenator@nicopure.com

Mr. William Venator, Vice President of Manufacturing
Nicopure Labs, LLC
5909 NW 18th Drive
Gainesville, Florida 32653

RE: Warning Letter W121-179 (Significant Non-Complier)
EPA/DEP ID: FLD 054 061 049
Alachua County – Hazardous Waste

Dear Mr. Venator:

A hazardous waste compliance inspection was conducted at your facility on April 29, 2021. During this inspection, possible violations of Chapters 376 and 403, Florida Statutes (Fla. Stat.), and Chapter 62-730, Florida Administrative Code (Fla. Admin. Code), were observed.

During the inspection, Department personnel noted the following:

- The facility did not mark one satellite and two central hazardous waste accumulation containers with an indication of the hazards of the contents.
- The facility did not conduct weekly inspections of two hazardous waste central accumulation areas.
- The facility did not label two containers as "hazardous waste."
- The facility did not label two containers of hazardous waste with the accumulation start date.
- There was a small quantity of hazardous waste accumulating in a spill pallet under a hazardous waste accumulation container.
- Two central accumulation areas were missing required emergency equipment.

- The facility did not submit a Quick Reference Guide to emergency responders when the Contingency Plan was amended and did not amend the Contingency Plan when the list of emergency coordinators changed.

Violations of Florida Statutes or administrative rules may result in liability for damages and restoration, and the judicial imposition of civil penalties, pursuant to Sections 376.121 and 403.121, Florida Statutes.

Please contact Bonnie Bradshaw at (904) 256-1638, or via email at Bonnie.Bradshaw@FloridaDEP.gov, within 15 days of receipt of this Warning Letter to arrange a meeting to discuss this matter. The Department is interested in receiving any facts you may have which might assist in determining whether any violations have occurred. You may bring anyone with you to the meeting that you feel could help resolve this matter.

Please be advised that this Warning Letter is part of an agency investigation, preliminary to agency action in accordance with Section 120.57(5), Florida Statutes. We look forward to your cooperation in completing the investigation and resolving this as soon as possible.

Sincerely,



Gregory J. Strong
District Director

Attachment: Final Inspection Report

cc: FDEP-NED: Bonnie Bradshaw, Cheryl Mitchell, Joni Petry, DEP_NED
Christopher Gilbert, Alachua County EPD - cgilbert@alachuacounty.us



**Florida Department of
Environmental Protection
Hazardous Waste Inspection Report**

FACILITY INFORMATION:

Facility Name: Nicopure Labs LLC
On-Site Inspection Start Date: 04/29/2021 **On-Site Inspection End Date:** 04/29/2021
ME ID#: 22938 **EPA ID#:** FLD054061049
Facility Street Address: 5909 NW 18th Dr, Gainesville, Florida 32653-1639
Contact Mailing Address: 5909 NW 18th Drive, Gainesville, Florida 32653
County Name: Alachua **Contact Phone:** (352) 729-3662

NOTIFIED AS:

LQG (>1000 kg/month)

WASTE ACTIVITIES:

Generator: LQG **Used Oil:** Used Oil **Universal Waste:** Indicate types of UW generated and/or accumulated at the facility: **Generate/Accumulate:** Batteries, Mercury Containing Lamps **Maximum quantity of UW handled or transported at any time:** Less than 5,000 kg (11,000 lbs); Small Quantity Handler (SQH)

INSPECTION TYPE:

Routine Inspection for LQG (>1000 kg/month) Facility
Routine Inspection for Used Oil Generator Facility

INSPECTION PARTICIPANTS:

Principal Inspector: Bonnie M Bradshaw, Inspector
Other Participants: Bob Hiltabidel, Facility Manager

LATITUDE / LONGITUDE: Lat 29° 42' 30.0202" / Long 82° 20' 45.472"

NAIC: 312230 - Tobacco Manufacturing

TYPE OF OWNERSHIP: Private

Introduction:

Nicopure Labs, LLC (Nicopure, the facility) was inspected April 29, 2021, as a hazardous waste compliance inspection. Nicopure's last hazardous waste inspection was a joint inspection conducted by the DEP and EPA on May 19, 2016. The facility is operating as a Large Quantity Generator (LQG) of hazardous waste. The facility notified as an LQG on February 7, 2020. The facility holds an Industrial User Wastewater Discharge Permit (IUDP,#16-001) issued by Gainesville Regional Utilities (GRU) which expires August 17, 2021.

Nicopure manufactures and distributes liquid solutions containing nicotine, flavored liquids and/or cannabidiol (CBD) that are used in electronic cigarettes. The liquid solution consists of a solution containing propylene glycol (PG), vegetable glycerin (VG) and varying concentrations of nicotine ranging from 0-36 mg or CBD. The liquid solutions are also available without nicotine/CBD and in multiple proprietary flavors. Nicopure offers two types of electronic vapor devices that are manufactured outside of the facility.

Nicopure has a 110,000 square foot facility on 17 acres. The facility currently has 29 employees working staggered shifts from 6:00 am to 5:00 pm Monday through Friday. Evolution Properties II, LLC, a related company, owns the building and property. The facility is connected to city water and sewer. The Receiving Area, 90-day Hazardous Waste Accumulation Area (HWAA), Clean Room Area, Warehouse, R & D Laboratory, H2 Room and Maintenance Shop were inspected. Tori Goodwin (DEP), Bob Hiltabidel (Nicopure), Kenneth Stamler, Jr. (Nicopure) and Roxanne Borer (Nicopure) were present throughout the inspection.

Inspection Date: 04/29/2021

Process Description:**Receiving Area**

Products enter the building through the Receiving Area. Products include raw materials for the manufacturing process, electronic cigarette components, bottles, caps, labeling materials, etc. Raw materials may be staged and/or tested by the internal quality team prior to being accepted into the warehouse.

The facility representatives explained that isopropyl alcohol is used on paper wipes to wipe down surfaces and equipment throughout the facility. Red, 35 to 55-gallon trash cans are designated throughout the facility as satellite accumulation containers and are used to collect the waste nicotine contaminated wipes and debris. The wipes are managed as P075 hazardous waste. There was one 55-gallon satellite container used for accumulation of waste nicotine contaminated wipes and debris. The container was empty at the time of inspection, but was closed and properly labeled.

The facility is reminded that a maximum of 2.2 pounds of solid acute hazardous waste, one quart of liquid acute hazardous waste or 55 gallons of non-acute hazardous waste may be accumulated in a Satellite Accumulation Area (SAA). Any excess of these quantities should be dated with the date the excess amount began accumulating and relocated to the 90-day HWAA or shipped off site to a permitted facility within three calendar days. Contents of the satellite containers are transported to the 90-day HWAA on Mondays, Wednesdays and Fridays.

The 90-day HWAA, described below, is also housed in the Receiving Area.

90-day HWAA

The 90-day HWAA is located in a section of the Receiving Area (Photo 1). Waste from throughout the facility is brought to this location before being transported off-site. According to Mr. Hiltabidel, waste is transported approximately every 85-86 days. The following containers were observed accumulating:

- (4) 1-cubic yard gaylord boxes of P075 solid hazardous waste
- (1) 275-gallon tote of P075 hazardous waste rinsate
- (2) 5-gallon carboys of D001/P075 liquid hazardous laboratory waste
- (1) box of universal waste spent bulbs
- (2) 5-gallon carboys of universal waste spent lithium batteries
- (1) 5-gallon bucket of universal waste spent lithium batteries
- (3) boxes of spent ink cartridges
- (1) 5-gallon bucket of circuit boards
- (1) box of USB battery chargers/cords

All containers were closed, properly labeled and marked with the accumulation start date. There was a fire extinguisher, eye wash, spill kit and "No Smoking" sign in the area.

The facility representative explained that spills throughout the facility are cleaned up by trained personnel using a mobile spill cart that is managed as an SAA (Photo 2). The cart is stored in the HWAA. There was one bag of P075 solid spill cleanup material accumulating on a mobile cart at the time of inspection. The bag was closed and properly labeled.

Clean Room Area

The Clean Room Area was under construction during the previous inspection. The Clean Room Area consists of a Gowning Area, GC Laboratory, a Nicotine Base Room, Mixing Room, Production Lines 1 and 2, Boxing Room, Sink Room, an Airlock Corridor between the Boxing and Sink Room, and a Pre-Clean Area, all further described below. The Clean Room Areas were observed through the glass observation windows. Some areas were not inspected due to a lack of observation windows.

Gowning Area

In the Gowning Area, employees don and doff Personal Protective Equipment (PPE) such as Tyvek suits, gloves, booties, masks, etc., prior to entering or upon exiting the Clean Room Area. There was one 35-gallon

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satellite container for the collection of spent PPE located in the Gowning Area. The container was closed and properly labeled.

GC Laboratory

This laboratory is equipped with a gas chromatograph, flame ionization detector and mass spectrometer used for analyzing nicotine concentrations, screening ingredients and testing new ingredients. Solvents used include methanol, acetonitrile and ethyl acetate. This laboratory is currently not frequently used and there was no waste accumulating at the time of inspection.

Nicotine Base Room

Nicotine formulations are mixed to various concentrations in the Nicotine Base Room. The facility representative stated that there is one 35-gallon satellite container located in the room. This area was not inspected.

Mixing Room

The nicotine, CBD and/or flavor formulations are blended in this room. PG and VG are combined with nicotine and/or flavors, in specific percentages, and dispensed into 5-gallon carboys. The carboys are then mixed in a mixing device. The formulations are taken either directly to the Production Lines for packaging, or to the Warehouse, described below, where they may steep for a period of time. CBD products are formulated and filled by hand, by chemists, in very small volumes. There was one 55-gallon satellite container used for accumulation of waste nicotine contaminated wipes and debris. The container was closed and properly labeled. The room was equipped with an eyewash, fire extinguisher and spill control materials.

The facility representative explained that carboys that have been emptied of nicotine and/or formulations may be used in the Production Line purge process, described below, or stored in the Warehouse, described below, for reuse. Occasionally, damaged containers or containers which held discontinued products are triple-rinsed in the Sink Room, described below, before disposal as solid waste. Empty containers of CBD are triple-rinsed in the Sink Room. All three rinses are collected and placed into Tote 1, located just outside of the Clean Room Area in the Warehouse, described below. The CBD residual appears to be a non-hazardous waste and is managed in Tote 1 due only to the fact that the SDS states "do not let product enter drains." RCRA-empty containers of flavors are triple-rinsed in the Sink Room due only to the presence of strong odors. All three rinses are discharged to Sink 1 which drains directly to the sewer lines discharging to the POTW. The containers are then disposed of as solid waste.

Production Lines 1 and 2

Formulations are brought from the adjacent Mixing Room or the Warehouse, described below, to Production Line 1 or 2 and pumped into the dispensing units. The formulations are then pumped into bottles and capped. Production Line 1 accommodates smaller sized bottles, and Production Line 2 accommodates larger sized bottles. There were three 35-gallon satellite containers and two 35-gallon satellite containers in Production Line 1 and 2, respectively, used for accumulation of waste nicotine contaminated wipes and debris. The containers were closed and properly labeled. The SAAs were equipped with eyewashes, fire extinguishers and spill control equipment.

The facility representative explained that the production lines need to be purged between different formulations, or as otherwise needed. The purge frequency is dependent upon production. Water, placed in the now emptied formulation carboy, is used to conduct multiple purge cycles concurrently with triple-rinsing of the carboy. The empty carboy is filled with water which is then run through the lines. The rinsate is drained back into the 5-gallon carboy. The first purge cycle rinsate is then emptied into Tote 1, located just outside of the Clean Room Area in the Warehouse, described below. Purge cycle rinsate from all additional purge cycles is discharged to Sink 2, located in the Sink Room described below, that discharges to Tote 2, located adjacent to Tote 1.

Boxing Room

In the Boxing Room, trays of bottles from the Production Lines are loaded into transport boxes and taken for labeling in the Warehouse, described below. The facility representative stated that no waste is generated in this area. This area was not inspected.

Inspection Date: 04/29/2021

Sink Room

There are two sinks located in the Sink Room. The facility representative explained that carboys or containers that have been emptied of nicotine, CBD, flavors, formulations and/or purge cycle rinsate may be triple rinsed in the Sink Room prior to reuse or disposal. Domestic, inert waste and all rinses from the rinsing of RCRA empty flavor containers are discharged to Sink 1 which is plumbed directly to sewer lines discharging to the POTW. Sink 2 is piped to Tote 2, located just outside of the Clean Room Area in the Warehouse, described below. Rinsate generated from the second and third rinses of nicotine/formulations carboys is discharged to Sink 2 that is piped to Tote 2. Water used for the first rinse of nicotine/formulations and all rinses from empty CBD containers is dispensed in the Sink Room, but the rinsate is hand-carried and collected in Tote 1, located adjacent to Tote 2 in the Warehouse. This area was not inspected.

Airlock Corridor

There is a corridor between the Boxing Room and Sink Room. There were four 55-gallon containers used for consolidation of waste from the other Clean Room Area satellite accumulation containers. This area was being managed as an SAA, but should have been managed as a Central Accumulation Area (CAA). All of the containers were closed, properly labeled and had been accumulating less than 90 days. There was no fire extinguisher, spill kit or eyewash present in the area [40 CFR 262.252(c)].

Pre-Clean Area

The Pre-Clean Area acts as a staging area for various products. The facility representative stated that there is one 35-gallon satellite container used for accumulation of waste nicotine contaminated wipes and debris in the room. This area was not inspected.

Warehouse

Products brought from the Receiving Area for storage, Mixing Room formulations being steeped prior to packaging, and carboys for reuse are stored on the Warehouse shelves. Employees also print bottle labels, apply the labels, assemble retail "kits," box products and ship products in the Warehouse. Labels are printed using Canon 034 Black and HP LaserJet CE390A-X-XC-XD ink cartridges. The cartridges contain an electronic chip. Empty or damaged print cartridges are taken to the HWAA. The facility has been labeling the cartridges as "Universal Waste," but is reminded that electronic waste does not meet the definition of universal waste. Damaged or defective lithium ion batteries used in the e-cigarette components are taken to the HWAA for management as universal waste.

Occasionally, damaged bottles or expired/off-specification e-liquid may be generated. Products that can't be repackaged or reclaimed are collected in containers and managed as P075 solid hazardous waste. The facility is reminded that hazardous wastes that are liquid or contain free liquids are prohibited from being landfilled. No such waste was observed in the Warehouse at the time of inspection.

Tote 1 and Tote 2 are located just outside of the Clean Room Area in the Warehouse. Tote 1 is used to accumulate the wastewater generated by the first purge of the Production Lines, first rinse of empty formulation/nicotine carboys and all rinses of CBD containers (Photo 3). Mop water from the Clean Room Area and mop water generated from spill cleanup of nicotine-containing products is also placed into this tote. Facility representatives stated that the period of time it takes to fill the tote can vary from approximately 24 hours to 1 month, depending on production. Tote 1 is currently managed as P075 hazardous waste and transferred to the HWAA for off-site disposal. The tote was closed, but not labeled as "Hazardous Waste" [40 CFR 262.17(a)(5)(i)(A)] with an indication of the hazards of the contents [40 CFR 262.17(a)(5)(i)(B)] and was not dated with an accumulation start date [40 CFR 262.17(a)(5)(i)(C)]. There was a small quantity of the hazardous waste liquid accumulating in the secondary containment spill pallet (Photo 4) [40 CFR 262.251].

Tote 2 is piped to Sink 2 in the Sink Room (Photo 5). The second and third rinses from empty containers of nicotine/formulations and/or purge cycles are discharged to Sink 2 and collected in this tote. Facility representatives stated that the period of time it takes to fill the tote can vary from approximately 24 hours to 1 month, depending on production. The facility holds an IUDP issued by GRU which allows discharge of wastewater that meets the permit limits of 60 mg/L nicotine and 275 gal/day. Once full, the tote is tested by the internal laboratory to ensure compliance with the facility's discharge permit limits. Enthalpy Analytical, LLC, a

Inspection Date: 04/29/2021

third-party laboratory, is also used to test the wastewater monthly. If the wastewater meets the discharge limits, the tote is transported to another section of the warehouse where it is discharged to the POTW via a gravity fed flexible hose (Photo 6), under the domestic sewage exclusion in 40 CFR 261.4(a)(1). If the wastewater does not meet the discharge permit limits, the tote would be transferred to the HWAA for management as P075 hazardous waste. The tote was closed, but not labeled as "Hazardous Waste" [40 CFR 262.17(a)(5)(i)(A)] with an indication of the hazards of the contents [40 CFR 262.17(a)(5)(i)(B)] and was not dated with an accumulation start date [40 CFR 262.17(a)(5)(i)(C)]. The tote should be managed as hazardous waste until the point the waste is actually discharged to the POTW.

Although not currently managed as such, these totes constitute a CAA. A fire extinguisher and eyewash were present, but spill control equipment was not located in the area [40 CFR 262.252(c)].

The facility representative stated that during testing prior to permit issuance, Tote 1 was also analyzed. However, Tote 1 consistently did not meet the discharge requirements and is therefore managed as hazardous waste.

R&D Laboratory

The R&D Laboratory is located in a walled and glassed area of the Warehouse and is operated as a clean room. The Laboratory is equipped with high-performance liquid chromatography unit used for quality monitoring of nicotine and CBD products. The machine uses either acetonitrile or ethyl acetate, but is currently using acetonitrile (flashpoint: 42.8°F). There was one 5-gallon carboy satellite container accumulating waste at the time of inspection. The container was closed and labeled as "Hazardous Waste," but was not labeled with an indication of the hazards of the contents [40 CFR 262.15(a)(5)]. The facility representative stated that the waste is managed as D001/P075 hazardous waste. Vials used for solution preparation are managed as D001/P075 hazardous waste. The facility is reminded that if ethyl acetate or another F-listed solvent is used in this process, that these wastes would also carry the F003 hazardous waste code. The Laboratory Chemist stated that solvents are not used on wipes in the laboratory. A fire extinguisher, eyewash and spill control materials were available in the area.

H2 Room

The H2 Room is a specially designed flammable containment room used for the storage of the flavorings and isopropyl alcohol. There was no waste observed accumulating in this area.

Maintenance Shop

Routine equipment maintenance and plastic part fabrication is performed in or out of the Maintenance Shop. Minor painting operations are performed with latex, water-based paint. The facility representative stated that solvents are not used and that no paint was currently present on site. The facility is reminded that a hazardous waste determination should be performed on any container of paint managed as a waste or paint contaminated debris. Paint may be ignitable or contain RCRA toxic constituents.

WD-40 and Office Depot Cleaning Duster are sprayed directly on equipment from an aerosol can. There were no waste aerosol cans observed at the time of the inspection. The facility is reminded that even when spent, aerosol cans may contain liquid product and/or flammable propellants which can cause the aerosol can to be a D001 and/or other hazardous waste. Additionally, aerosol cans with broken or clogged nozzles may be considered a hazardous waste. Unless an aerosol can is completely empty of both liquid and propellant, as defined in 40 CFR 261.7, it should not be thrown into the trash. All unusable and spent aerosol cans should either be safely punctured and properly drained into a closed and properly labeled container which should then be managed as hazardous waste, or be placed unpunctured into a closed and properly labeled container which should then be managed as a hazardous waste. Alternatively, the facility may choose to manage hazardous waste aerosol cans as a universal waste, provided they meet the requirements of 40 CFR 273. The facility representative stated that they plan to manage any non-RCRA empty cans as universal waste.

Facility personnel replace fluorescent light bulbs or LED light bulbs. Spent bulbs are managed as universal waste. There were no bulbs accumulating in the Maintenance Shop at the time of inspection.

Air Centers of Florida and Ingersoll Rand are the contractors used for air compressor maintenance. This maintenance generates used oil, used oil filters and oily rags. These waste streams are managed by the

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contractors. No other used oil or used oil filters are generated by the facility, with the exception of a small amount of used oil generated by non-routine pressure washer maintenance in 2020. Various contractors are used for forklift maintenance. This maintenance generates spent lead acid batteries which are managed by the contractors.

Records

The facility is currently operating as a Large Quantity Generator (LQG) of hazardous waste.

The facility generates the following routine hazardous waste streams:

Solid Nicotine Waste – P075

Nicotine Wastewater – P075

Acetonitrile/Nicotine Laboratory Waste – D001/P075

The facility representative stated that a shipment is scheduled every 85-86 days. Records indicate that shipments may sometimes be more frequent. Hazardous waste is currently transported by Triumvirate Environmental Services, Inc. (FLD 981 018 773) to Ross Incineration Services, Inc. (OHD 048 415 665) or Elemental Environmental Solutions, LLC (ARD 006 354 161). Freehold Cartage, Inc. (NJD 054 126 164) is used as a secondary transporter. The last shipment of hazardous waste was February 17, 2021.

Records indicate that the Tote 2 nicotine rinsate is discharged to GRU between every one to 24 days and that no exceedances of the permitted limits have occurred during the review period. Records indicate that Tote 2 had been accumulating for 15 days.

Records indicate that universal waste bulbs, universal waste batteries, circuit boards, ink cartridges, USB chargers/cords and other electronic waste are self-transported to the Alachua County Hazardous Waste Center for proper disposal. The facility is reminded that registration as a universal waste lamp transporter may be required unless collecting from generators of 10 or less spent lamps per month who do not accumulate more than 100 kilograms or lamps at one time.

Records indicate weekly inspections of the 90-Day HWAA located in the Receiving Area were being conducted as required. Weekly inspections of the Tote 1 and Tote 2 nicotine rinsate, being operated as a CAA in the Warehouse, were not being conducted [40 CFR 262.17(a)(1)(v); 62-730.160(3), FAC]. It is the facility's policy to inspect all SAAs weekly. Therefore, weekly inspections of the area in the Airlock Corridor being operated as a CAA were being conducted, but documentation did not meet the requirements of the regulations [62-730.160(3), FAC].

A review of the facility's Contingency Plan (CP) indicated that although the CP was amended in 2019 to update the emergency coordinator list, a Quick Reference Guide was not submitted to emergency responders [40 CFR 262.262(b)]. In addition, the emergency coordinator list was not current at the time of inspection [40 CFR 262.263(d)]. The secondary emergency coordinator was no longer employed at the facility.

Records of manifests, training and hazardous waste determinations reviewed appeared to be in order.

Copies of Northeast District's Hazardous Waste Generator Workshop PowerPoint training documents and other workshop files that may be useful can be found here:

<ftp://ftp.dep.state.fl.us/pub/outgoing/NED%20-%20HazWaste/LQG%20WORKSHOP/>

Please note that you cannot access this site using Chrome so you will have to use another browser such as Edge, Firefox, Internet Explorer, etc.

Please note that 40 CFR 262.18 requires re-notification for LQGs as follows:

LQGs - notify by March 1 of each even-numbered year, or via submittal of a Biennial Report.

For Outstanding Items of Potential Non-Compliance

Please review the following section – New Potential Violations and Areas of Concern. This section includes potential violations observed at your facility during this inspection. For any potential violations below that have not been corrected, please refer to the Corrective Action for each item that is suggested to bring your facility into

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compliance. Once the corrective action has been completed, please send documentation to the Principal Inspector listed on page 1 of this Inspection Report. This documentation includes, but is not limited to, photos of corrected items, manifests, SDSs or other documents that will show that each potential violation has been fully addressed.

New Potential Violations and Areas of Concern:**Violations**

Type:	Violation
Rule:	262.15(a)(5)
Explanation:	R&D Laboratory: One 5-gallon carboy of D001/D075 hazardous waste was not marked with an indication of the hazards of the contents.
Corrective Action:	No further action is required. The facility returned to compliance via an email dated July 8, 2021.
Type:	Violation
Rule:	262.17(a)(1)(v)
Explanation:	Clean Room Area Airlock Corridor: Weekly inspections of the Central Accumulation Area containing four 55-gallon containers of P075 hazardous waste were being conducted, but documentation did not include all the required elements. Warehouse: Weekly inspections of the Central Accumulation Area containing two totes of P075 hazardous waste were not being conducted.
Corrective Action:	No further action is required. The facility returned to compliance via an email dated July 5, 2021, and received July 6, 2021.
Type:	Violation
Rule:	262.17(a)(5)(i)(A)
Explanation:	Warehouse: Two 275-gallon totes of P075 hazardous waste were not labeled with the words "Hazardous Waste."
Corrective Action:	No further action is required. The facility returned to compliance via an email dated July 8, 2021.
Type:	Violation
Rule:	262.17(a)(5)(i)(B)
Explanation:	Warehouse: Two 275-gallon totes of P075 hazardous waste were not labeled with an indication of the hazards of the contents.
Corrective Action:	No further action is required. The facility returned to compliance via an email dated July 8, 2021.
Type:	Violation
Rule:	262.17(a)(5)(i)(C)
Explanation:	Warehouse: Two 275-gallon totes of P075 hazardous waste were not labeled with the accumulation start date.
Corrective Action:	No further action is required. The facility returned to compliance via an email dated July 8, 2021.
Type:	Violation
Rule:	262.251
Explanation:	Warehouse: There was a small quantity of P075 hazardous waste accumulating in the secondary containment spill pallet under Tote 1 in the Central Accumulation Area.

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Corrective Action: No further action is required. The facility returned to compliance via an email dated July 5, 2021, and received July 6, 2021.

Type: Violation

Rule: 262.252(c)

Explanation: Clean Room Area Airlock Corridor: The Central Accumulation Area (CAA) did not have a fire extinguisher, spill kit or eyewash.
Warehouse: The CAA did not have a spill kit.

Corrective Action: Clean Room Area Airlock Corridor: No further action is required. The facility returned to compliance via an email dated July 5, 2021, and received July 6, 2021.
Warehouse: No further action is required. The facility returned to compliance via an email dated July 8, 2021.

Type: Violation

Rule: 262.262(b) , 262.263(d)

Explanation: The facility did not submit a Quick Reference Guide to emergency responders when the Contingency Plan was amended and did not amend the Contingency Plan when the list of emergency coordinators changed.

Corrective Action: No further action is required. The facility returned to compliance via an email dated July 8, 2021.

PHOTO ATTACHMENTS:

Photo 1

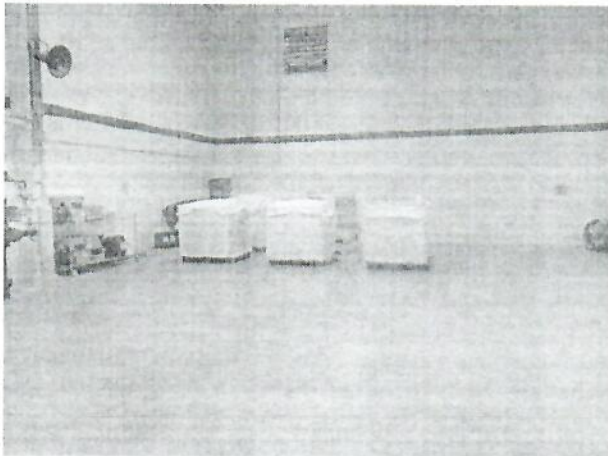


Photo 2



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Photo 3

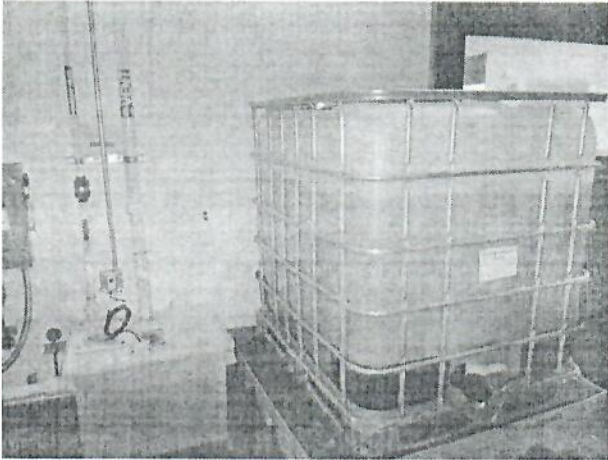


Photo 4

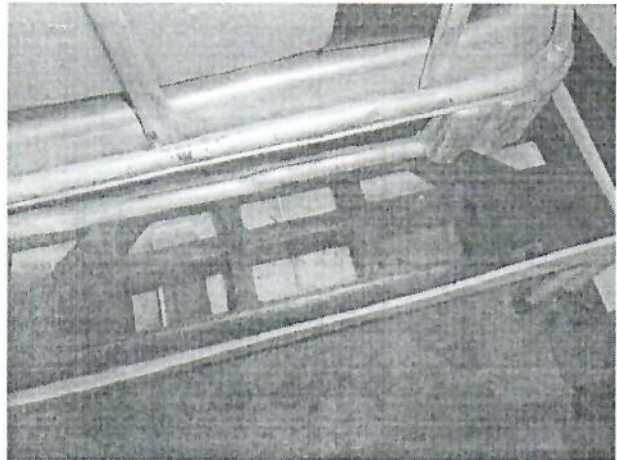


Photo 5

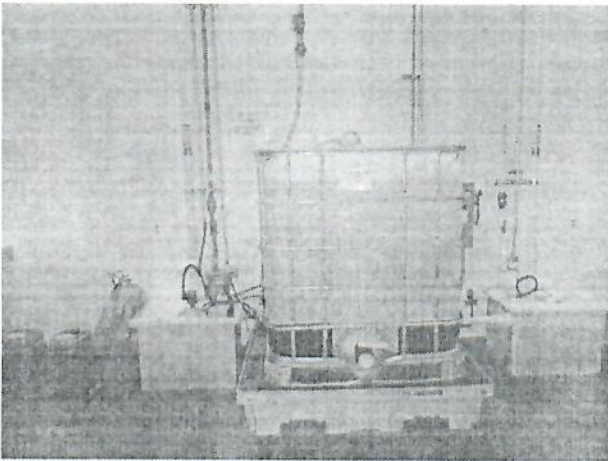
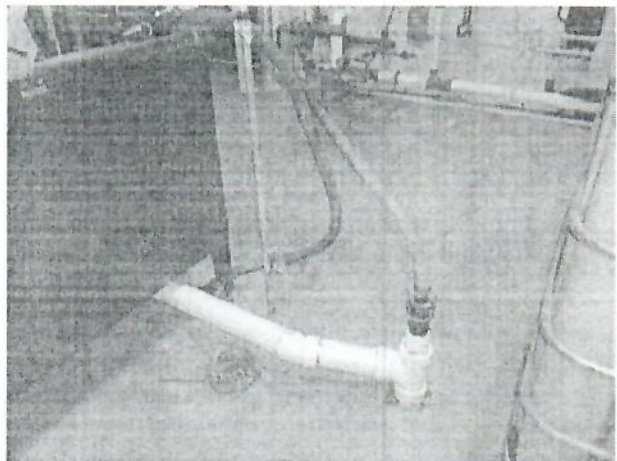


Photo 6



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1.0: Pre-Inspection Checklist**Requirements:**

The requirements listed in this section provide an opportunity for the Department's inspector to indicate the conditions found at the time of the inspection. A "Not Ok" response to a requirement indicates either a potential violation of the corresponding rule or an area of concern that requires more attention. Both potential violations and areas of concern are discussed further at the end of this inspection report.

Note: Checklist items with shaded boxes are for informational purposes only.

Item No.	Pre-Inspection Review	Yes	No	N/A
1.1	Has the facility notified with correct status? 262.18(a)	✓		
1.2	Has the facility notified of change of status? 62-730.150(2)(b)			✓
1.3	Did the facility conduct a waste determination on all wastes generated? 262.11	✓		

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Signed:

A hazardous waste compliance inspection was conducted on this date, to determine your facility's compliance with applicable portions of Chapters 403 & 376, F.S., and Chapters 62-710, 62-730, 62-737 & 62 -740 Florida Administrative Code (F.A.C.). Portions of the United States Environmental Protection Agency's Title 40 Code of Federal Regulations (C.F.R.) 260 - 279 have been adopted by reference in the state rules under Chapters 62-730 and 62-710, F.A.C

Bonnie M Bradshaw

Inspector

Principal Investigator Name

Principal Investigator Title



DEP

07/13/2021

Principal Investigator Signature

Organization

Date

Bob Hiltabidel

Facility Manager

Representative Name

Representative Title

Nicapure Labs LLC

Organization

NOTE: By signing this document, the Site Representative only acknowledges receipt of this Inspection Report and is not admitting to the accuracy of any of the items identified by the Department as "Potential Violations" or areas of concern.

Report Approvers:

Approver:

Bonnie M Bradshaw

Inspection Approval Date:

07/13/2021