8.0 ENVIRONMENTAL ASSESSMENT

The environmental assessment is prepared in accordance with 21 C.F.R part 25 (Environmental impact consideration); subpart D (Preparation of Environmental Documents); section 25.40 – Environmental assessment, the National Environmental Policy Act of 1969 (NEPA) and the U.S. Environmental Protection Agency regulation. The information in this document helps to provide evidence that the manufacturing process of PurNic- E-Liquid Nicotine Propylene Glycol (PurNic- PG) and use of the said product by consumers does not result in any significant impact to the environment in accordance with the standard 25.40(a) and NEPA of 1969.

8.1 Requested Action

Nicotine River is submitting a Tobacco Product Master File (TPMF) submission of PurNic- E-Liquid Nicotine Propylene Glycol (PurNic- PG) to the United States Food and Drug Administration (USFDA).

8.2 Need for Action

Nicotine River is submitting a Tobacco Product Master Files ("TPMF") to the Food and Drug Administration ("FDA") for the PurNic- E-Liquid Nicotine Propylene Glycol (PurNic - PG) pursuant to USFDA guidance on how to submit and reference Tobacco product Master file.

8.3 Identification of PurNic- PG e-liquid

The PurNic- E-Liquid Nicotine Propylene Glycol (PurNic - PG) e-liquid product is being manufactured at Nicotine River and is being sold to consumers in the U.S. The PurNic - PG identification information is described in Table (50) below:

Table 68: Product Identification Information

Brand Name	PurNic
Product Name	E-Liquid Nicotine Propylene Glycol
Manufacturer	**Nicotine River** **River Supply Co.** 2535 Conejo Spectrum St, Thousand Oaks CA 91320 Phone: (805) 375-0401 Email: info@nicotineriver.com Web: https://riversupplyco.com
Category	ENDS
Subcategory	E-liquid
Package type	HDPE F-Style containers with white resin added for increased rigidness and opacity.
Package quantity	1 bottle

Characterizing flavor	NA	
E-liquid volume per package	150mL, 500mL, 1 Liter, 1 gallon, 2.5 gallon and 55 gallon	
Nicotine concentration	100mg/ml	
Universal Product Code	4974132546551	N-PUR-NSS-100V-1 gallon
	1343611869628	N-PUR-NSS-100V 1 Liter
	2336152349543	N-PUR-NSS-100V 2.5 gallon
	7184975596430	N-PUR-NSS-100V 55 gallon
	5902872817616	N-PUR-NSS-100V-150 mL
	1339548460670	N-PUR-NSS-100V-500 mL

8.3.1 Type of Tobacco Product

PurNic- E-Liquid Nicotine Propylene Glycol (PurNic- PG) is considered as an Electronic nicotine delivery system (ENDS); subcategory as e-liquid under section 910 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

8.3.2 Tobacco Product Number

The tobacco product number assigned PurNic- E-Liquid Nicotine Propylene Glycol (PurNic- PG) by FDA along with package size are described in Table- 51 below:

Table 69: Product Name and Tobacco Product Number

Product Name	Package Size	Tobacco Product Number
Smooth Nicotine Base 100mg/ml PG	1 gallon	TP99SZ5YH
Smooth Nicotine Base 100mg/ml PG	1 Liter	TP99SZ5YG
Smooth Nicotine Base 100mg/ml PG	2.5 gallons	TP99SZ5YJ
Smooth Nicotine Base 100mg/ml PG	55 gallons	TP99SZ5YM
Smooth Nicotine Base 100mg/ml PG	150 mL	TP99SZ5YC
Smooth Nicotine Base 100mg/ml PG	500 mL	TP99SZ5YF

8.3.3 Description of Product Packaging

The PurNic- E-Liquid Nicotine Propylene Glycol (PurNic- PG) is available in a 150mL, 500mL, 1L, 1 Gallon, 2.5 Gallon and 55 Gallon containers. Product packaged in white HDPE bottles utilizing heat induction capping. All HDPE white plastics with white resin added for rigidness and opacity.

8.3.4 Description of Manufacturing Facility

The PurNic- PG e-liquid is being manufactured at a federally licensed manufacturing facility located at 2535 Conejo Spectrum St, Thousand Oaks CA 91320. A map of the manufacturing facility is shown in Figure (8) and a close-up view is shown in Figure (9) below. The

manufacturing facility is registered with the U.S Environmental Protection Agency (EPA) with Identification (EPA ID) number as CAR000286898.

The manufacturing facility is located within an industrial zone and is serviced by municipal water and sewer. The building is constructed with concrete floors; steel/tin corrugated outside walls and ceilings with insulation. The building has a total floor space of 45000 square feet. The building contains a dedicated manufacturing area, storage area for raw materials and finished goods.

The designated boundaries of the manufacturing facility do not include any recognized or controlled fisheries or wetlands. Both the manufacturing and warehouse facilities are supplied with power from a local utility provider. Water service is provided by the municipality. Run-off, sewage and grey water discharges are collected through a sanitary piping system and fed to the municipality-owned sewage treatment and processing center. The manufacturing facility does not come under a U.S. Fish and Wildlife Service Critical Habitat area for threatened and endangered species. The manufacturing facility exists in a rural area and is not required to have any water or air emission permits. There are no plans for the facility expansion, zone change or land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use.

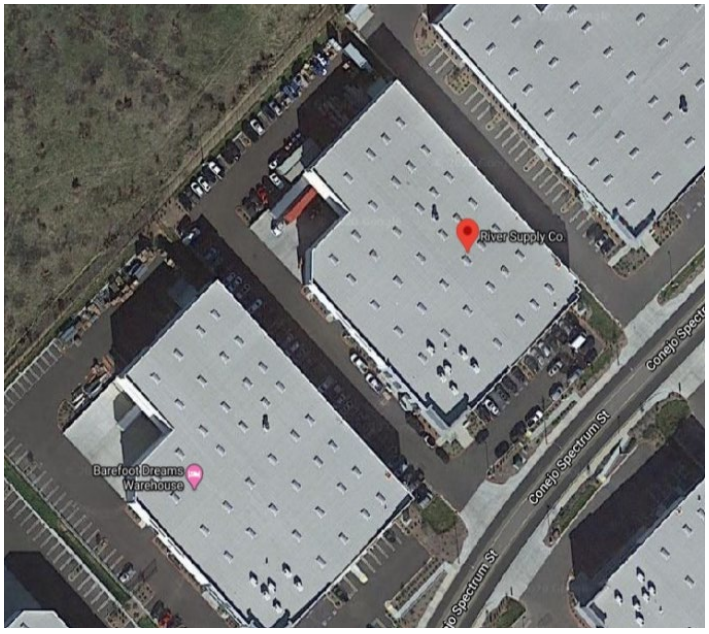


Figure 9: Location of Manufacturing Facility

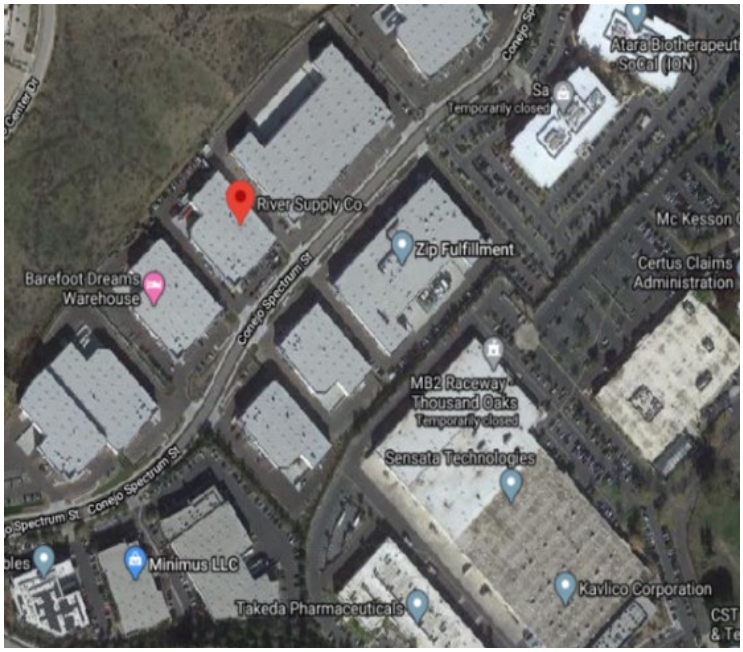


Figure 10: Close-up View of Manufacturing Facility

8.3.5 Location of Use

The PurNic- E-Liquid Nicotine Propylene Glycol (PurNic- PG) is intended to be distributed and sold throughout the United States and is expected to be used in manufacturing of e-liquid product utilized in electronic nicotine delivery system device.

8.3.6 Location of Disposal

The PurNic- E-Liquid Nicotine Propylene Glycol (PurNic- PG) is intended to be consumed during manufacturing of an e-liquid to be used in Electronic Nicotine Delivery System device. Accordingly, because PurNic- PG is intended to be consumed rather than used and subsequently discarded, it is expected that the product, itself, is unlikely to be disposed of as waste. If and when a user does dispose of the PurNic- PG, it is expected to be disposed of as hazardous waste. The packaging for the PurNic- PG will be disposed of as MSW in landfills or will be recycled, as is the case with any other consumer product packaging. The distribution of waste from disposal of the PurNic- PG is expected to correspond to the use pattern for the product. Moreover, the disposal of the PurNic- PG is expected to be identical to competitive products marketed in accordance with FDA's current premarket review compliance policy for deemed products.

8.4 Environmental Introduction due to the Proposed Action

Environmental introduction to a) Manufacturing, b) use of the tobacco product, and c) disposal following the use of the product are described in the following section.

8.4.1 Environmental Introduction as a Result of Manufacturing

The PurNic- E-Liquid Nicotine Propylene Glycol (PurNic- PG) will be manufactured in U.S. in full compliance with the applicable environmental laws and permitting requirements in the jurisdiction. No significant environmental impacts are expected from manufacturing of the PurNic- PG under the proposed action.

The PurNic- PG is currently being manufactured subject to FDA's current compliance policy for deemed tobacco products that were on the market as of August 8, 2016, and thus, the continued manufacture of this product will not require an expansion of the manufacturing facility where the product is produced. It will not require additional resources to handle manufacturing waste disposal associated with the PurNic- PG, nor will new or expanded landfills be required to accommodate manufacturing waste due to the product. Likewise, no new environmental controls will need to be implemented due to the manufacture of the PurNic- PG e-liquid. The manufacturing facility is equipped to produce the PurNic- PG in compliance with applicable environmental laws and regulations. Moreover, because there will be negligible changes to air emissions – including greenhouse gases – and water discharge due to manufacture of the PurNic- PG, new emissions and discharge permits will not be needed for the manufacturing facility. The detailed calculation and explanation are provided in Appendix-1 (confidential appendix).

Nicotine River manufacture e-liquid by mixing liquid Nicotine, Propylene Glycol (USP grade). This mixture is packed into white HDPE Opaque bottle utilizing heat induction capping. Table (52) below provides design features and material for PurNic- PG e-liquid.

Table 70: Design features and material for PurNic- PG e-liquid

Brand Name	PurNic- PG
Nicotine source	USP grade Nicotine extract
Package type	Product packaged in white HDPE bottles utilizing heat induction capping.

Labeling	Paper and synthetic inkjet receptive label materials, including matte and glossy stocks

Nicotine in this product is USP grade extract procured from the vendor. This is not expected to produce or generate or cause or add to the manufacturing waste.

Other waste includes shipping containers from the delivery of the raw materials, packaging material and label stationeries. The paper waste is being recycled. Raw materials are expected to be disposed of as hazardous waste by a Enviroserve-Savage company. Any kind of environmental release from raw materials, packaging materials and labeling stationeries is not expected. Further, other materials that are not referred above such as plastic scrap are disposed of via contracted waste disposal service. Other administrative waste is also disposed correspondingly. Nicotine River do not discharge any materials onto land or into a body of water.

The quantity of manufacturing waste produced will be proportional to sales. The character and nature of wastes are not expected to change as a result of introducing the e-liquid. The maintenance and cleaning of the manufacturing equipment necessitate the use of commercially available lubricants, cleaning chemicals and compounds. Nicotine River only maintains a minimum inventory of hazardous and nonhazardous compounds or chemicals. All waste oils, solvents or chemicals are collected and disposed of or recycled through a contracted service.

During the e-liquid manufacturing process, no toxic or hazardous emissions are released. The U.S. Environmental Protection Agency (EPA) - Toxic Release Inventory (TRI) for 2018[11], which shows total on-site water release as 3.5 million pounds and land release as 12.9 million pounds in California state (where the manufacturing facility is located).

[11] TRI Factsheet: State – California, 2018 Updated Dataset (released April 2020). EPA- United state environmental protection agency. https://enviro.epa.gov/triexplorer/tri_factsheet.factsheet_forstate?pstate=CA&pyear=2018&pParent=TRI&pDataSet=TRIQ1

Quick Facts for 2018

	California	United States
Number of TRI Facilities:	1,212	21,612
Total Production-Related Waste Managed:	295.2 million lbs	32.1 billion lbs
Total On-site and Off-site Disposal or Other Releases:	34.4 million lbs	3.8 billion lbs
Total On-site:	23.8 million lbs	3.3 billion lbs
• Air:	7.3 million lbs	606.0 million lbs
• Water:	3.5 million lbs	195.1 million lbs
• Land:	12.9 million lbs	2.5 billion lbs
Total Off-Site:	10.5 million lbs	466.5 million lbs

Figure 11: Facilities and Nature of Releases in California in the year 2018

Quick Facts for 2018

	Industry	United States
Number of TRI Facilities:	28	21,612
Total Production–Related Waste Managed:	1.5 million lbs	32.1 billion lbs
Total On–site and Off–site Disposal or Other Releases:	948.3 thousand lbs	3.8 billion lbs
Total On–site:	631.0 thousand lbs	3.3 billion lbs
• Air:	563.8 thousand lbs	606.0 million lbs
• Water:	2.8 thousand lbs	195.1 million lbs
• Land:	64.3 thousand lbs	2.5 billion lbs
Total Off–site:	317.3 thousand lbs	466.5 million lbs

Figure 12: Tobacco Facilities and Nature of Releases in the United States in the year 2018

The following figures represent releases of chemicals to the environment in the State of California [12]. A "release" of a chemical means that it is emitted to the air or water, placed in some type of land disposal, or transferred off-site for disposal or release. Total on-site release in California from the year 2003 to 2008 is depicted in figure (12) below. Production related waste is constantly decreasing as is evident in figure (13) below.

[12] Data Source: National Analysis Dataset. 2018 Updated (released April 2020)
https://enviro.epa.gov/triexplorer/industry.html?pYear=2018&pLoc=3122&pParent=TRI&pDataSet=TRIQ1

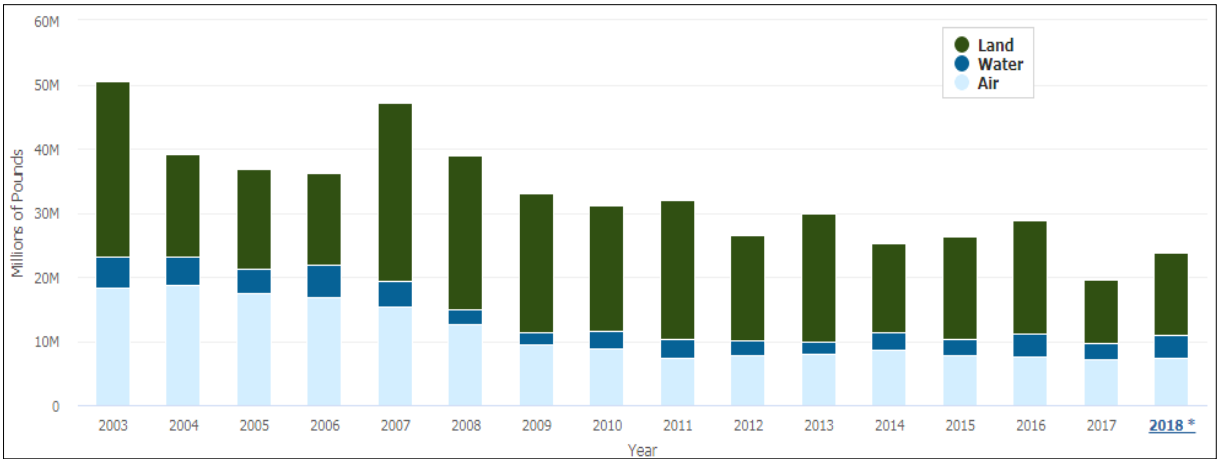


Figure 13: Total On-site Releases by Environmental Medium in California from the year 2003 to 2018

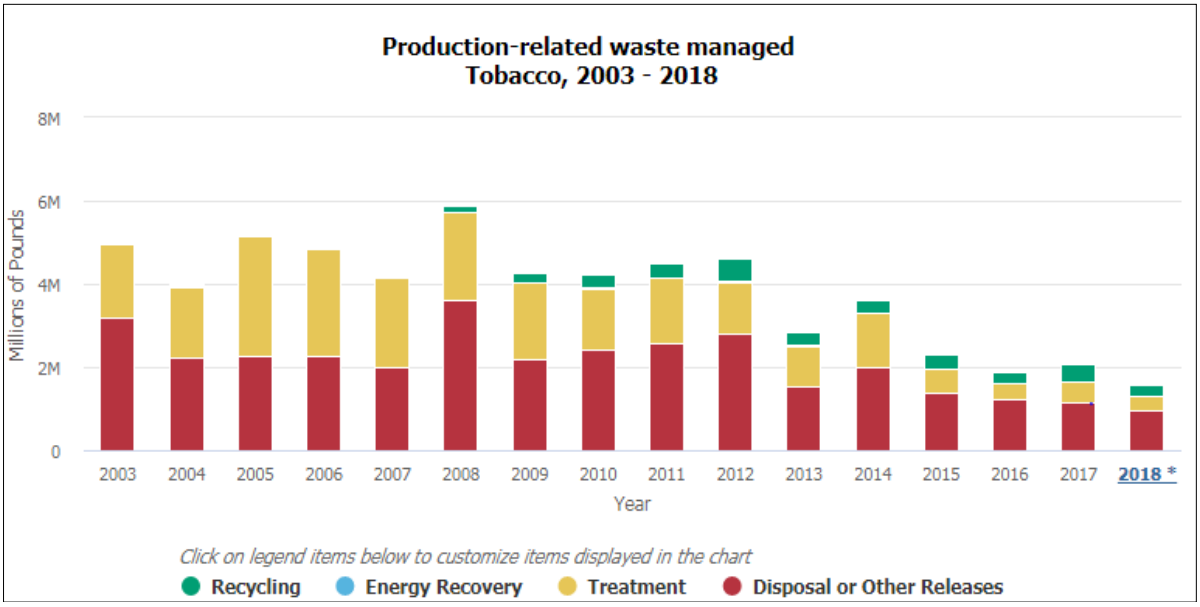
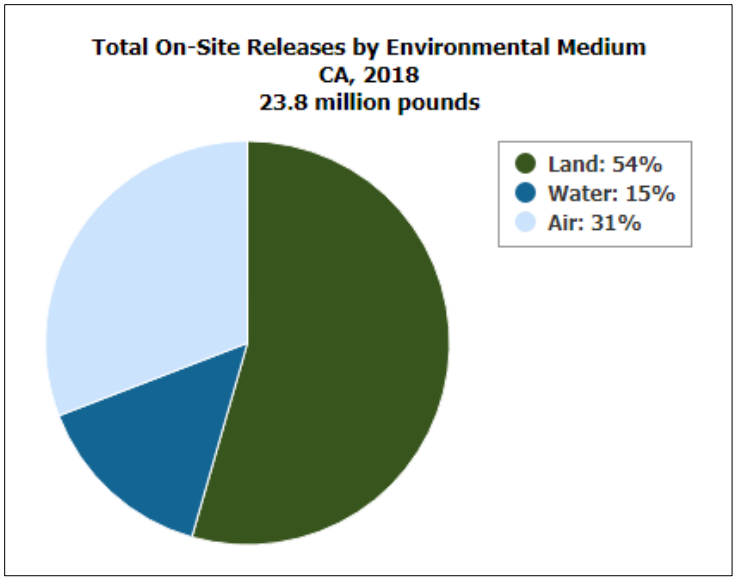


Figure 14: Production-related waste managed Tobacco from the year 2003 to the year 2018

The following figures represent releases of chemicals to the environment in the State of California and their disposal medium. Also, the top five chemicals released in air and water are depicted in Figure (16). These chemicals are not released from Nicotine River.



Total Releases
Tobacco, 2003 - 2018

Total Releases
Tobacco, 2018

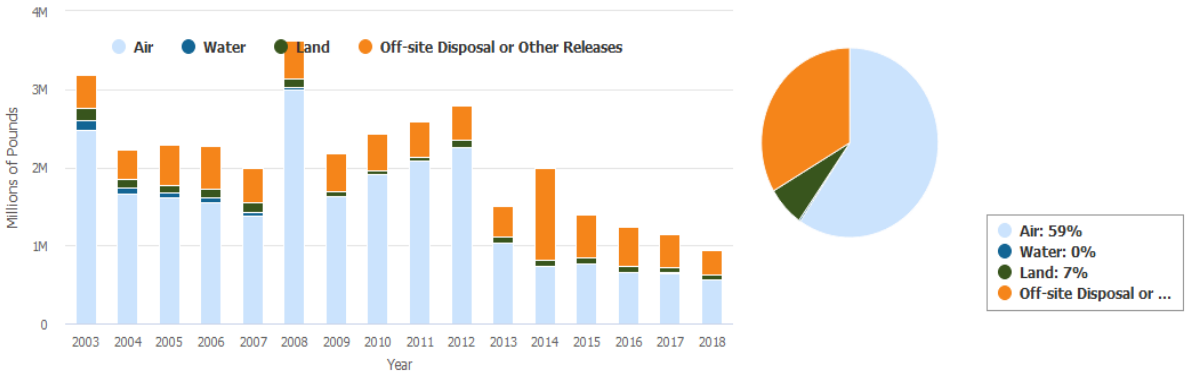


Figure 15: Total On-site Releases by Environmental Medium in California in year 2018

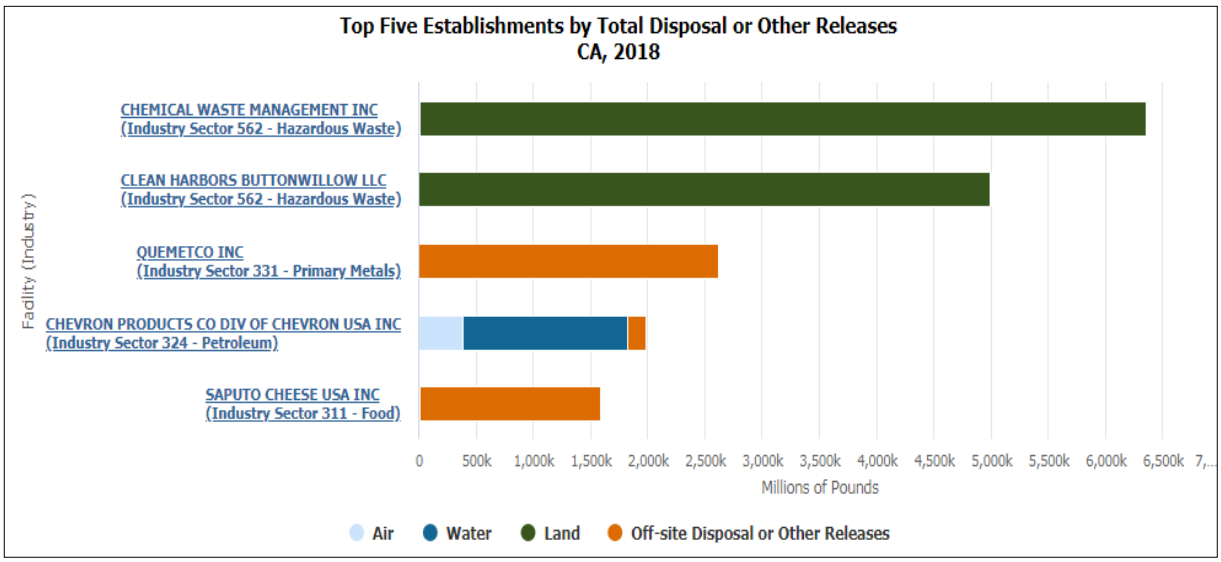


Figure 16: Top Five Establishments by Total Disposal or Other Releases in California in year 2018

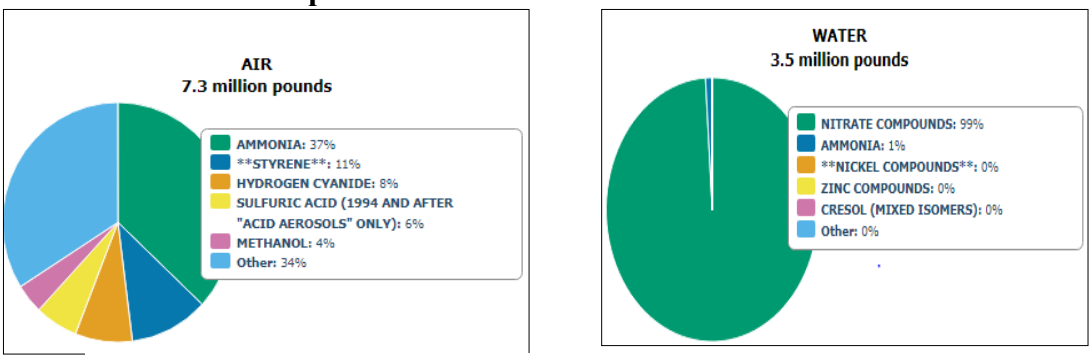


Figure 17: Total Five Chemicals Released to Air and Water in California in the year 2018

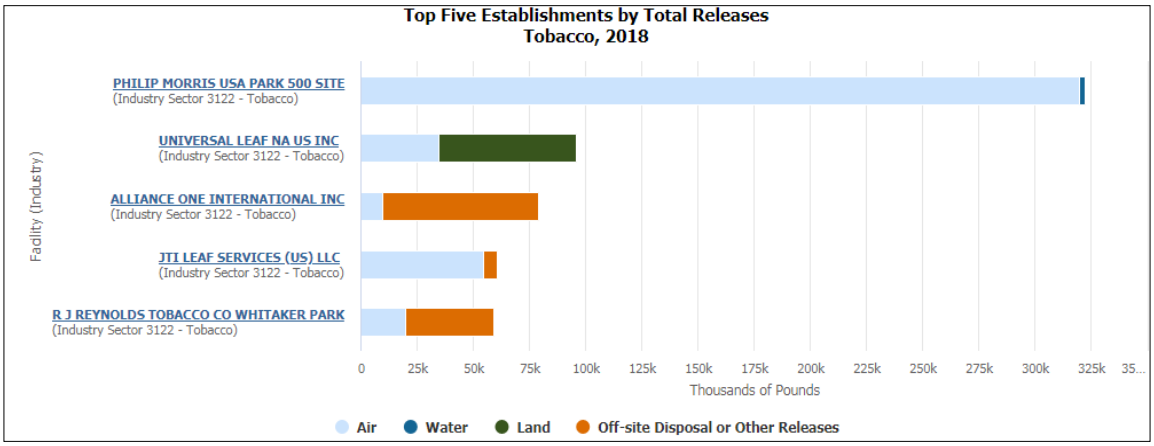


Figure 18: Top Five Establishments by Total Releases Tobacco in the year 2018

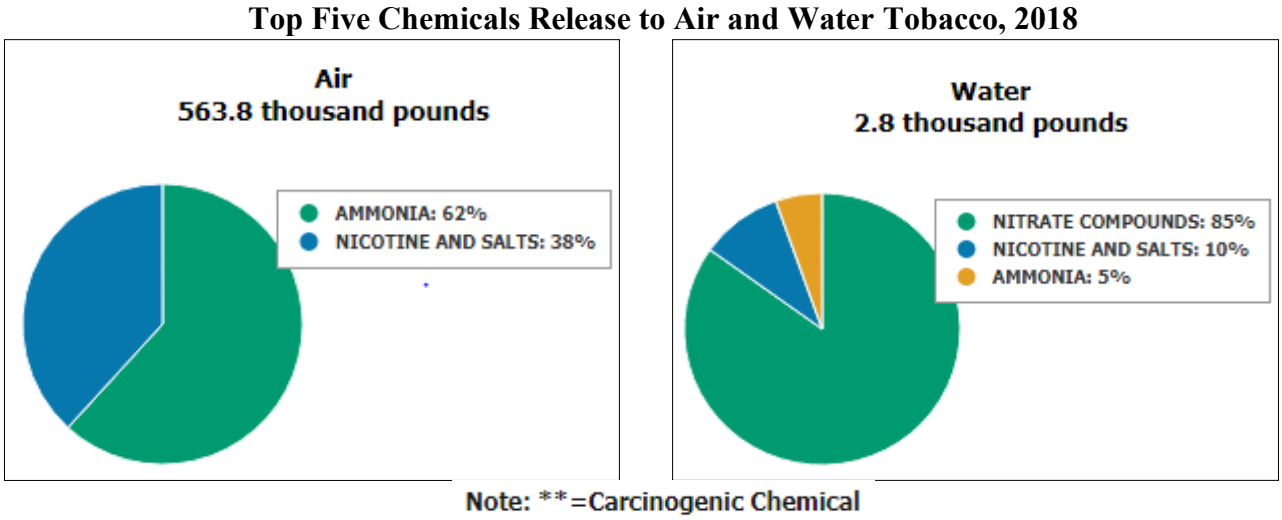


Figure 19: Top Five Chemicals Released to Air and Water, Tobacco in the year 2018

Nicotine River is in compliance with all federal, state, and local environmental regulations. The Nicotine River manufacturing facility is not in a critical habitat area. The production and use are not known to affect endangered species. The production and use of e-liquid are also not known to affect the trade of endangered species as outlined by the Convention on

International Trade in Endangered Species of Wild Flora and Fauna [1] in compliance with U.S. Endangered Species Act (ESA) [2]. The final product is packaged in white HDPE bottles utilizing heat induction capping and shipped to the distributor in a shipper box. There is no additional packaging provided for this product for retail sale.

The e-liquid products are not expected to significantly affect the current e-liquid manufacturing emission from the Nicotine River production facility. Wastes will be transferred to landfills or recycled in the same manner as those generated from the manufacturing of the current e-liquid products in the facility.

8.4.2 Environmental Introduction as a Result of Use of the Tobacco Products

The environmental introduction resulting from the use of the PurNic- PG also is not expected to differ in any appreciable way from the environmental introduction due to the use of alternative, competitive products. The PurNic- PG will compete with and replace existing market share for other e-liquids or alternative tobacco products already on the market. As described in detail in the accompanying TPMF, the PurNic- PG will be used in manufacturing of e-liquid being used in ENDS devices. This resultant e-liquid product is marketed to traditional cigarette smokers and users of other combustible tobacco products. Accordingly, the environmental introduction resulting from the use of the PurNic- PG is expected to be substitutional for any environmental introductions from the traditional cigarette market. In fact, the use of combustible tobacco products has fallen and is forecasted to continue to decline in part because of the emergence of ENDS products as an alternative [3].

The results of the studies published in the literature are summarized below. These studies demonstrate that the consumption of the most commonly used cigarette like e-cigarettes will have a negligible impact on air quality in most indoor environments. Consequently, the amount of release of material mass into the environment as a result of the use of the e-liquid is negligible compared to that of all smokeless tobacco products or snuff being used in the U.S. Therefore, the introduction of released substances from use of the PurNic- PG is negligible from the environment viewpoint.

1. McAuley, T. R., Hopke, P. K., Zhao, J., & Babaian, S. (2012). Comparison of the effects of e-cigarette vapor and cigarette smoke on indoor air quality. *Inhalation toxicology*, 24(12), 850-857.[4]

Context: Electronic cigarettes (e-cigarettes) have earned considerable attention recently as an alternative to smoking tobacco, but uncertainties about their impact on health and indoor air quality have resulted in proposals for bans on indoor e-cigarette use.

Objective: To assess potential health impacts relating to the use of e-cigarettes, a series of studies were conducted using e-cigarettes and standard tobacco cigarettes.

Methods and materials: Four different high nicotine e-liquids were vaporized in two sets of experiments by generic 2-piece e-cigarettes to collect emissions and assess indoor air concentrations of common tobacco smoke by-products. Tobacco cigarette smoke tests were conducted for comparison.

Results: Comparisons of pollutant concentrations were made between e-cigarette vapor and tobacco smoke samples. Pollutants included VOCs, carbonyls, PAHs, nicotine, TSNAs, and glycols. From these results, risk analyses were conducted based on dilution into a 40 m^3 room and standard toxicological data. Non-cancer risk analysis revealed, "No Significant Risk" of harm to human health for vapor samples from e-liquids (A-D). In contrast, for tobacco smoke, most findings markedly exceeded risk limits indicating a condition of "Significant Risk" of harm to human health. With regard to cancer risk analysis, no vapor sample from e-liquids A-D exceeded the risk limit for either children or adults. The tobacco smoke sample approached the risk limits for adult exposure.

Conclusions: For all byproducts measured, electronic cigarettes produce very small exposures relative to tobacco cigarettes. The study indicates no apparent risk to human health from e-cigarette emissions based on the compounds analyzed.

2. Gourdet, C. K., Chriqui, J. F., &Chaloupka, F. J. (2014). A baseline understanding of state laws governing e-cigarettes. Tobacco control, 23(suppl 3), iii37-iii40. [5]

Background: Electronic cigarettes (e-cigarettes) have been available for purchase in the USA since 2007 and have grown rapidly in popularity. Currently, there are no federal restrictions on e-cigarettes; therefore, any regulations are under the purview of state and/or local governments. This study examines state laws governing e-cigarettes through youth access restrictions, smoke-free air requirements and/or excise taxation.

Methods: Codified statutory and administrative laws, attorney general opinions, executive orders, and revenue notices and rulings effective as of 15 November 2013 for all 50 states and the District of Columbia, were compiled using Boolean searches in Lexis-Nexis and Westlaw. All laws were analyzed by two study authors to determine the presence and components of relevant provisions. Two categories of laws were

identified; (1) explicit e-cigarette laws and (2) laws focused on tobacco-derived and/or nicotine-containing products.

Results: Thirty-four states' laws address e-cigarettes either explicitly or as part of language applying to tobacco-derived or nicotine-containing products. Laws explicitly addressing e-cigarettes primarily focus on youth access (22 states) or smoke-free air (12 states); only Minnesota imposes an excise tax on e-cigarettes. Similarly, tobacco-derived or nicotine-containing products are primarily regulated through youth access restrictions (6 states), smoke-free air laws (5 states), or excise taxation (2 states).

Conclusions: In the current absence of federal law governing e-cigarettes, more than one-half of the total states in the U.S have taken the initiative to regulate these products. The opportunity exists for the remaining states to incorporate e-cigarette-related restrictions into their pre-existing tobacco control laws.

3. Long, G. (2014). Comparison of select analytes in exhaled aerosol from e-cigarettes with exhaled smoke from a conventional cigarette and exhaled breaths. International journal of environmental research and public health, 11(11), 11177-11191. [6]

Exhaled aerosols were collected following the use of two leading U.S. commercial electronic cigarettes (e-cigarettes) and a conventional cigarette by human subjects and analyzed for phenolics, carbonyls, water, glycerin and nicotine using a vacuum-assisted filter pad capture system. Exhaled breath blanks were determined for each subject prior to each product use and aerosol collection session. Distribution and mass balance of exhaled e-cigarette aerosol composition was greater than 99.9% water and glycerin, and a small amount (<0.06%) of nicotine. Total phenolic content in exhaled e-cigarette aerosol was not distinguishable from exhaled breath blanks, while total phenolics in exhaled cigarette smoke were significantly greater than in exhaled e-cigarette aerosol and exhaled breaths, averaging 66 μg/session (range 36 to 117 μg/session). The total carbonyls in exhaled e-cigarette aerosols were also not distinguishable from exhaled breaths or room air blanks. Total carbonyls in exhaled cigarette smoke was significantly greater than in exhaled e-cigarette aerosols, exhaled breath and room air blanks, averaging 242 μg/session (range 136 to 352 μg/session). These results indicate that exhaled e-cigarette aerosol does not increase bystander exposure for phenolics and carbonyls above the levels observed in exhaled breaths of air.

4. John W. Caraway, 2015. Secondhand Emissions in an Environmental Chamber after E-cigarette Vaping. Research and Development, R.J. Reynolds Tobacco Company, Winston Salem, NC, USA. 69th Tobacco Science Research Conference Naples, FL, USA, 20-23 September 2015. [7]

Selected secondhand smoke (SHS) constituents were evaluated in a 28 m3 unventilated environmental chamber after e-cigarette vaping or combustible cigarette smoking. Subjects were enrolled into 3 e-

cigarette groups (VUSE Original, VUSE Menthol, and a market sample) and 2 cigarette groups (leading non-menthol and leading menthol brands). Each group consisted of 11-12 subjects. Ten test sessions were conducted for each group (5 smoking/vaping and 5 non-smoking/non-vaping). Four subjects from a group were randomly selected to participate in each session. Sessions started with a 10-min background collection after subjects entered the chamber, followed by a 10-min ad libitum smoking/vaping period (or non-smoking/non-vaping). Subjects then exited the chamber, and a 120-min sample collection period was initiated. Real-time data collection was also performed throughout the entire test session.

Airborne concentrations of 25 SHS constituents were determined using methods validated according to the principles of Good Laboratory Practice (GLP). Analytes included formaldehyde, acetaldehyde, nicotine, benzene, toluene, glycerin, Propylene Glycol (PG), PM2.5, carbon monoxide and ammonia.

By design, test conditions resulted in SHS concentrations much higher than expected in real-world smoking environments. Even under these conditions, most SHS constituent levels after e-cigarette vaping were not statistically significantly different than after sessions without vaping. Generally in e-cigarette SHS levels were at least 95% lower than cigarettes. PG levels after vaping were categorized as higher, lower, or no different than after smoking, depending on the product comparison. Glycerin concentrations after vaping were higher than cigarette smoking. Although e-cigarette secondhand nicotine concentrations were higher than the non- vaping blank, they were 88-99% lower than cigarettes. The results demonstrate that consumption of the most commonly used cigarette-like e-cigarettes will have a negligible impact on air quality in most indoor environments.

Aerosol in an outdoor environment would disperse quickly with negligible impact to outdoor air quality. Any minute environmental introductions that could potentially occur when the PurNic- PG is used will be identical to the releases that already exist for competitive products that are currently being marketed. Moreover, the environmental introduction resulting from use of the PurNic- PG will have a negligible environmental impact because the market volume of the PurNic- PG is de minimize relative to the overall U.S. tobacco market (e.g., 216.9 billion cigarettes were sold by the major manufacturers in 2018) [8].

8.4.3 Environmental Introduction as a Result of Disposal Following Use of the Product

The environmental introduction resulting from the disposal of the PurNic- E-Liquid Nicotine Propylene Glycol (PurNic- PG) is expected to be negligible due to the understanding that the PurNic- PG will be fully consumed when used as intended, rather than used and disposed of. The environmental effects of disposal following the use of the e-liquid products result from:

A. Disposal of packaging material

B. Discarding the used e-liquid bottle

A. Disposal of packaging material

As such no packaging material is involved for retail products. Packaging material involved is in a shipment of the bottles would either entre in the recycling stream or be disposed of in MSW landfills. Disposal of packaging materials following use of the PurNic- PG will not require additional resources for waste disposal (e.g., new landfills or recycling centers)

Paper is known for its biodegradable characteristics, and cardboard packaging is expected to degrade upon disposal. However, assuming that the packaging is disposed of in a landfill we set forth below the relevant data regarding MSW generation in the U.S., as FDA has relied on in past environmental assessments for tobacco products. These data demonstrate that, on average, 4.51 pounds of waste per person is generated each day; 1.56 pounds of this is recycled and composted (for 2017) [9].

The information about trash generation in the United States, including details about the disposal of materials comparable to those used in cigarette products, can be informative about the disposal of e-liquid packing materials. Per capita, MSW generation increased from 4.48 pounds per person per day in 2015 to 4.51 pounds per person per day in 2017, which is one of the lowest since 1990.

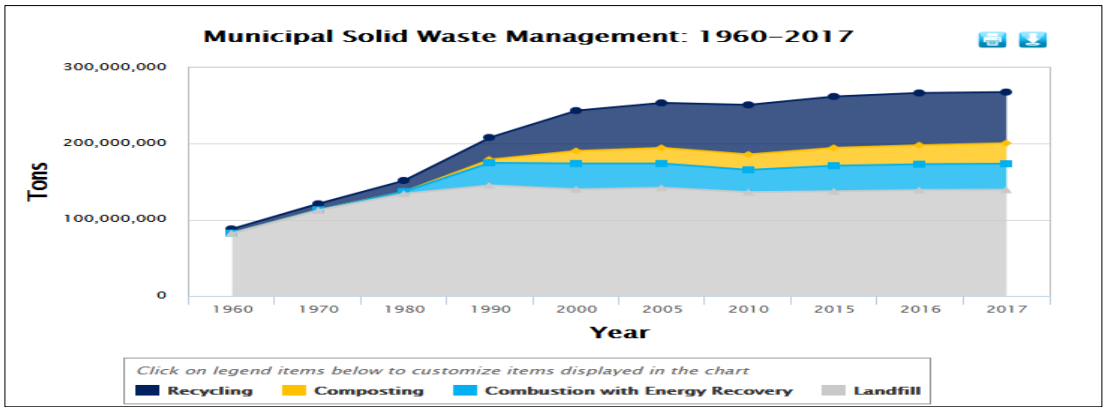


Figure 20: Municipal Solid Waste Management in the United States from the year 1960 to 2017

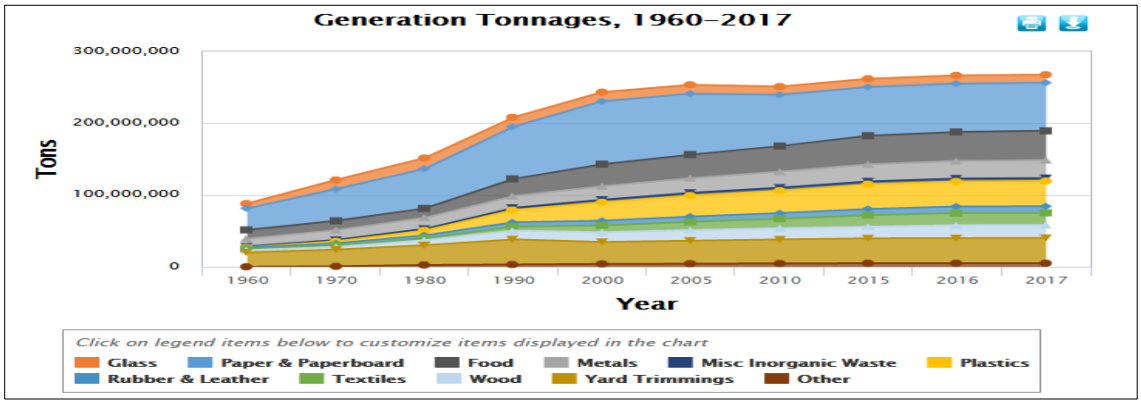


Figure 21: Generation Tonnages from the year 1960 to 2017

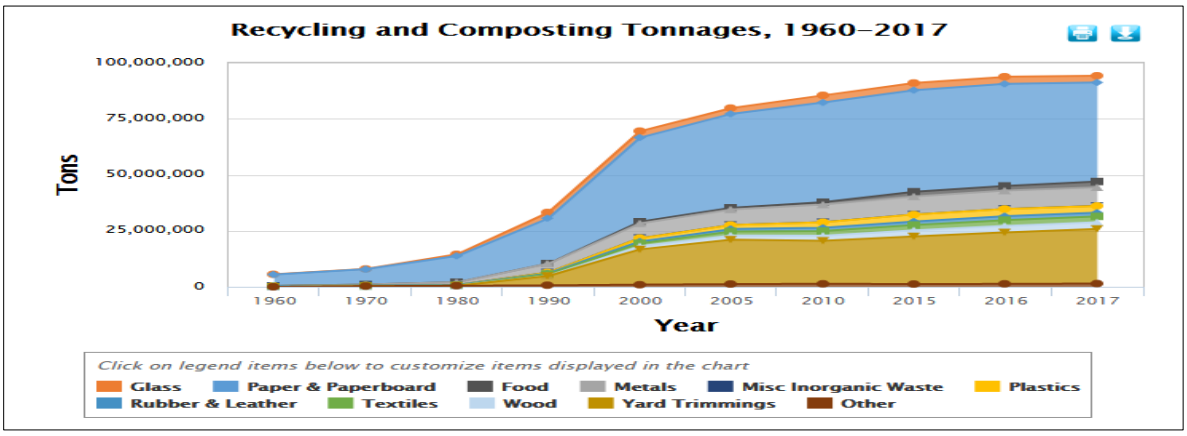


Figure 22: MSW Recycling Rates in the United States from the year 1960 to 2017

Measured by tonnage, the most-recycled or composted products and materials in 2017 were corrugated boxes (28.8 million tons), yard trimmings (24.4 million tons), mixed nondurable paper products (9.9 million tons), newspapers/mechanical papers (4.2 million tons), lead-acid batteries (3.2 million tons), major appliances (3.1 million tons), glass containers (three million tons), wood packaging (three million tons), tires (2.6 million tons), food (2.6 million tons), mixed paper containers and packaging (1.3 million tons) and selected consumer electronics (one million tons). Collectively, these products accounted for 92 percent of total MSW recycling and composting in 2017.

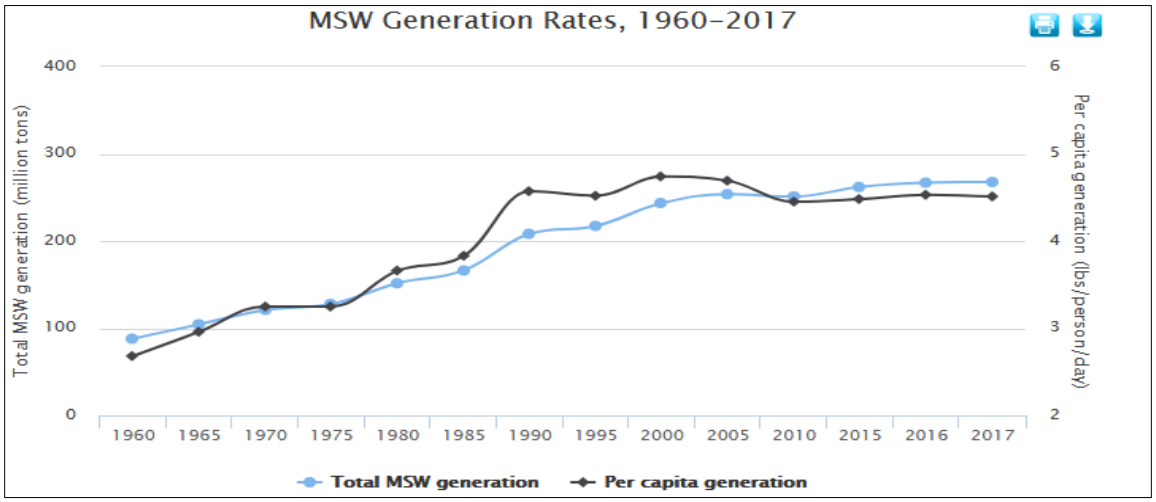


Figure 23: Municipal Solid Waste Generation Rates in the United States from 1960 to 2017

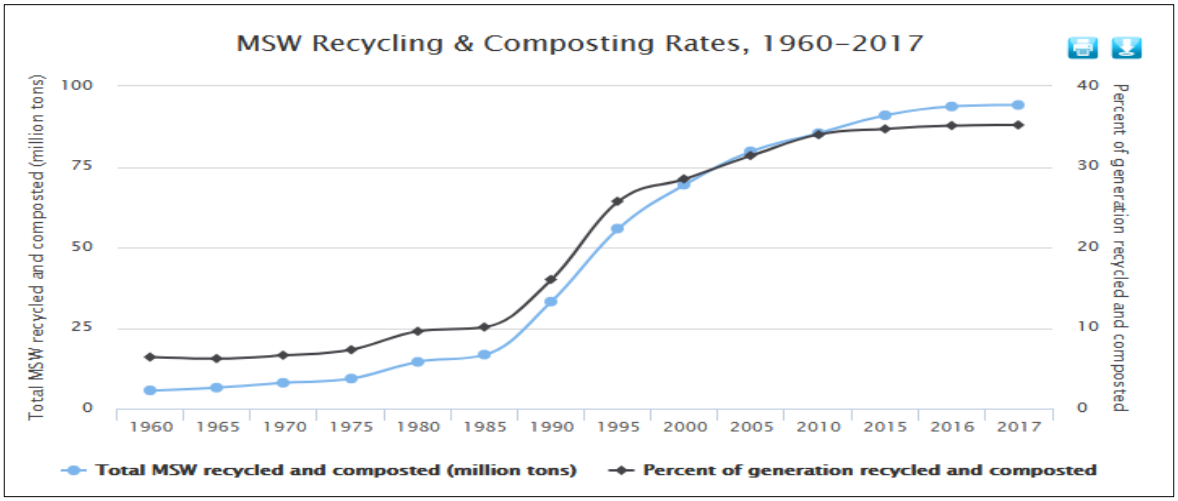


Figure 24: Municipal Solid Waste Recycling & Composting Rates in the United States from 1960 to 2017

When combusted, the shipper box yields ash, carbon dioxide, and water vapor, which are commonly found in MSW. This is expected to make up a very small portion of the total MSW currently combusted. The packaging for the PurNic- PG will not significantly alter emissions from properly operating MSW facilities, and, thus, does not threaten a violation of applicable emissions laws and regulations.

B. Discarding the used e-liquid bottle

The e-liquid product after use will be disposed of as hazardous waste or will be treated in the same manner as any other e-liquid products. The waste is expected to consist primarily of an empty bottle and their residual products. The amount of residual liquid is expected to be minimal. It is anticipated that the pattern of disposal will be the same as other e-liquid products.

8.5 Fate of New Materials Released into the Environment Due to the Proposed Action

Because the PurNic- E-Liquid Nicotine Propylene Glycol (PurNic- PG) has the same general characteristics of composition, use, and disposal as the competitive products already on the market, no new materials are expected to be released into the environment. As noted, the PurNic- PG has the same attributes as those e-liquid products currently in use in the U.S.

8.6 Environmental Effects of New Materials Released into Environment Due to Proposed Action

The PurNic- E-Liquid Nicotine Propylene Glycol (PurNic- PG) will be manufactured in accordance with all applicable regulations in its locality of manufacture.

As noted above, the PurNic- PG has the same general characteristics of composition, use, and disposal as competitive products already on the market; no new materials are expected to be released into the environment. Specifically, the manufacture, use, and disposal of the PurNic- PG is not anticipated to impact any species or critical habitat of any species identified under the Endangered Species Act

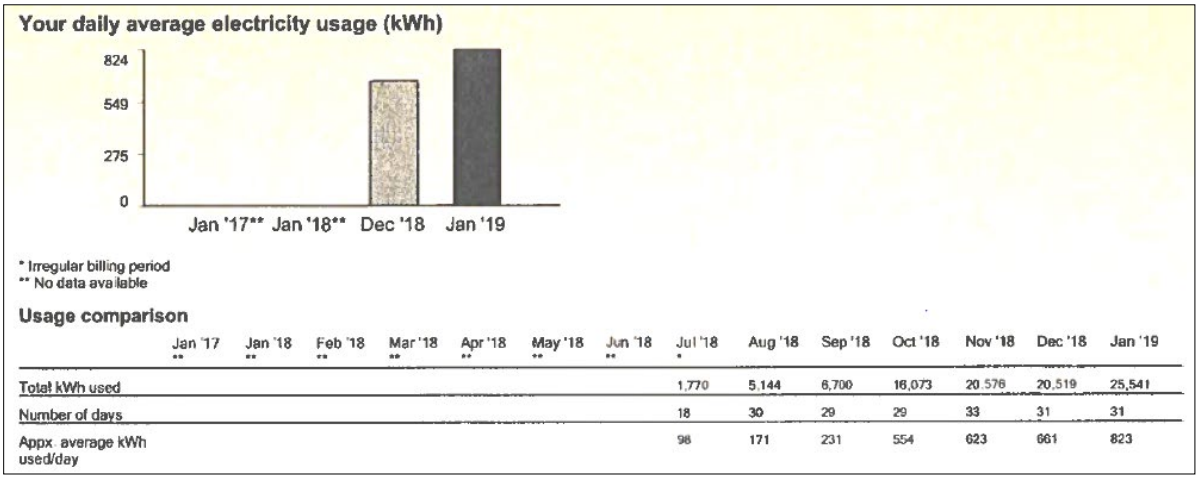
("ESA") or the Convention on International Trade in Endangered Species of Wild Flora and Fauna ("CITES"). The environmental effects of materials released based on the manufacture, use, and disposal of the PurNic- PG are insignificant.

8.7 External Impact on Community

Nicotine River manufacturing facility is located within an industrial zone. No residential housing and no retail operations currently exist within the boundaries of this facility.

8.8 Use of Resources and Energy

Because the PurNic™ Nicotine Propylene Glycol (PurNic - PG) is substitutional for other e-liquid and/or alternative tobacco products currently being marketed in the U.S., the use of resources and energy due to the proposed action is negligible. The daily electricity consumption and annual usage comparison of Nicotine River from the year 2018 to the year 2019 is provided below. Nicotine River continuously making efforts towards energy conservation and consumption reduction by utilizing low energy consumption devices or machineries which are in compliance with the energy standards.



Usage comparison

	Jan '17 **	Jan '18 **	Feb '18 **	Mar '18 **	Apr '18 **	May '18 **	Jun '18 **	Jul '18 *	Aug '18	Sep '18	Oct '18	Nov '18	Dec '18	Jan '19
Total kWh used								1,770	5,144	6,700	16,073	20,576	20,519	25,541
Number of days								18	30	29	29	33	31	31
Appx. average kWh used/day								98	171	231	554	623	661	823

Figure 25: Daily Electricity Consumption and Annual usage Comparison from the year 2018 to 2019

No environmental effects are anticipated due to proposed action as Nicotine River. is utilizing all manufacturing equipment in compliance with the energy star (wherever possible) which is run by the U.S. Environmental Protection Agency and U.S. Department of Energy.

8.9 Mitigation

Because this environmental assessment has not identified any adverse environmental impacts from the proposed use of PurNic- E-Liquid Nicotine Propylene Glycol (PurNic- PG), no mitigation measures have been developed.

8.10 Alternatives to Proposed Action

No adverse environmental impacts have been identified in this environmental assessment that would necessitate an alternative to the proposed action. If the proposed action is denied, the result would simply be the continued use of other tobacco products which are in compliance as per the FDA regulation standards. Such an action would have no environmental impact.

8.11 Confidential Appendix (Appendix 1)

- Chemical composition
- First and fifth year market volume projections for the PurNic- PG
- First and fifth year projections of waste of packaging materials.
- Calculation of Green House Gas generated from product related waste