

Comparative Aerosol HPHC Evaluation of Seven Flavors of a Temperature-Regulated Nicotine Salt-Based Connected ENDS Product with Combustible Tobacco Cigarettes

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ABSTRACT

The Glas G² ENDS (Glas) is a temperature-regulated nicotine salt pre-filled disposable pod connected system with two power settings, and age-gated technology, designed to minimize the combustion byproducts across a range of operating environments. Comparatively, combustible cigarettes can reach temperatures of 1000 degrees Celsius and consequently generate over seven thousand identified thermal degradation products including compounds characterized as Harmful and Potentially Harmful Constituents (HPHCs).

Seven different Glas e-liquids (three tobacco, two menthol, two non-characterizing; 50 mg/ml nicotine) were analyzed for HPHCs and compared to a 3R4F Kentucky Reference Cigarette and the market leading tobacco cigarette, Marlboro Gold. The Glas e-liquids and combustible tobacco cigarettes were vaped under intense puffing conditions.

No significant increase in the HPHC profile was observed with the two power settings, vaped under non-intense and intense conditions, therefore presenting minimal risk to the consumers.

On a per day use basis (total e-liquid consumption for Glas pods and cigarette use for tobacco products), there was a significant reduction in minor nicotine alkaloids (98%), carbonyl compounds (95-99%), volatile organic compounds (VOCs) (99%), metals (45-95%).

On a product use per mg nicotine basis, carbonyl compounds, nicotine alkaloids, VOCs, and metals (cadmium and lead) levels were 95% to 99% lower and nickel was 25%-60% lower in the Glas pods compared with the 3R4F reference cigarette and Marlboro Gold.

This comparative HPHC analysis demonstrated that Glas test products in combination testing with the Glas G² device with two power settings yielded significantly lower HPHC compared to combustible tobacco cigarettes.

STUDY OVERVIEW

Two combustible tobacco cigarettes, Kentucky reference, 3R4F and Marlboro Gold are used as benchmarks in assessing the potential HPHC exposure of the seven Glas test articles (Table 1) relative to tobacco cigarette.

Table 1. Glas e-Liquid Products Tested

	Test Articles	Flavor	Nicotine Concentration
1	BLUE TOBACCO	Tobacco	50 MG/ML
2	BLONDE TOBACCO	Tobacco	50 MG/ML
3	SIGNATURE TOBACCO	Tobacco	50 MG/ML
4	FRESH MENTHOL	Menthol	50 MG/ML
5	CLASSIC MENTHOL	Menthol	50 MG/ML
6	SAPPHIRE	Non characterizing	50 MG/ML
7	GOLD 50	Non characterizing	50 MG/ML

GLASS DEVICE AND PRINCIPLE OF OPERATION

The Principle of Operation of the Glas ENDS product (G² ENDS) including a proprietary prefilled disposable pod containing proprietary nicotine+flavor e-liquids and battery device. The schematic design diagram and G² Glas power specifications are shown in Figure 1 and Table 2.

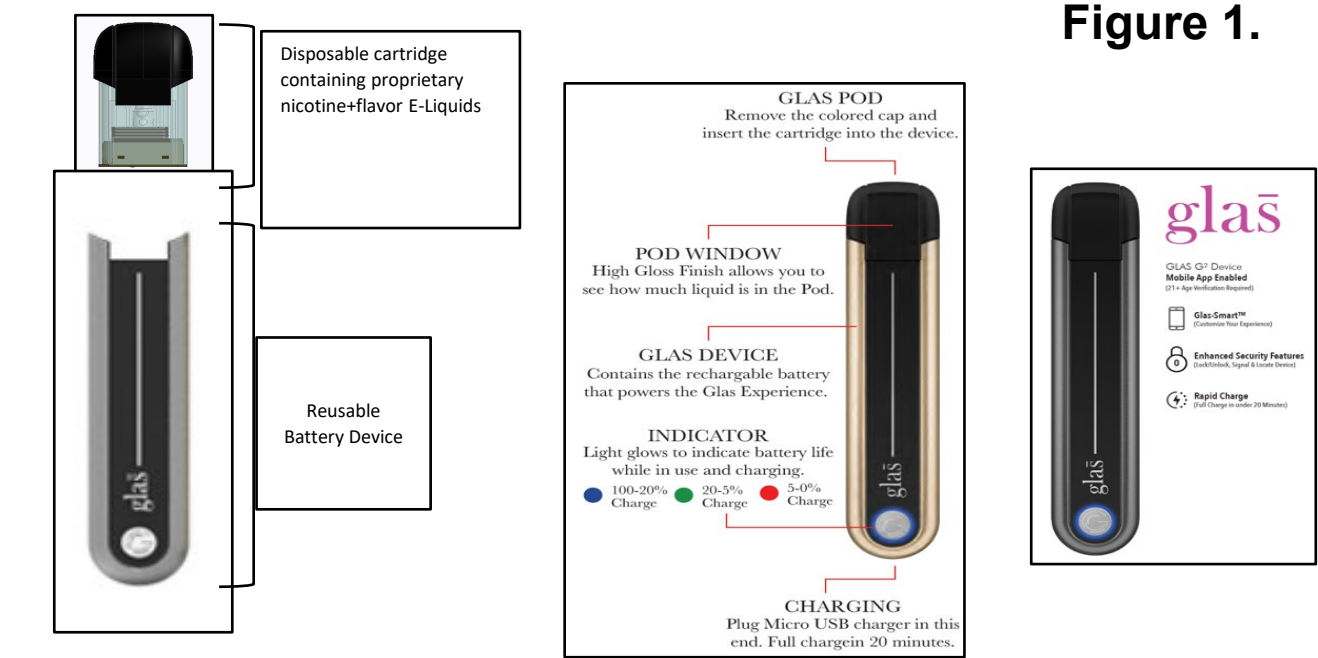


Figure 1.

Table 2. Glas G² Device Power Settings

Power Setting	Power during Puff
ECO	8 Watt for 0.5 second followed by 6W for the rest of the puff
STD	10 Watt for 0.3 second followed by 8W for the rest of the puff

METHODS: SAMPLES COLLECTION AND STUDY DESIGN

All HPHC testing were conducted at Enthalpy Analytical LLC with locations in Durham, North Carolina and Richmond, Virginia.

For aerosol generation, Glas G² device was used. Glas test articles were smoked under intense puffing regime (110/cc puff, 5 second puff duration, 30 second inter-puff interval). The 3R4F and Marlboro Gold cigarettes were smoked under Canadian intense conditions. These HPHC per puff values were calculated on a per cigarette basis using the average of 9.1 puffs per cigarette (Jaccard et al. 2019). For aerosol HPHC analysis, 7 replicates for each constituent analysis were measured as suggested by FDA guidelines.

For comparative purpose, since the HPHC constituents list of tobacco cigarettes and ENDS are different, the comparative analysis lists the common HPHC analytes.

Data Analysis:

To compare and demonstrate the realistic comparative daily HPHC exposure of Glas test articles relative to conventional tobacco combustible cigarette, Glas HPHC values were normalized by the daily upper limit (in mL) of the product use classified by flavors (Glas Clinical Study) and 14.1 cigarette consumption/day for conventional tobacco burning cigarette based on MMWR 2018 study. (Jamal et al. 2016).

For HPHC exposure on per mg nicotine basis, the HPHC constituents from the Glas test articles and tobacco cigarettes, 3R4F and Marlboro Gold, were normalized to nicotine content based on the estimated or reported consumption.

Glas Product Daily Use

The daily Glas product use (upper limit in mL) classified by flavors derived from the Glas Clinical Study in Table 3.

Table 3. The Estimated Upper limit (mL) Product Daily Use of Glas Test Articles

Glas Test Articles	Glas Device Power Settings	Estimated Median Daily Usage (mL/day)
BLUE TOBACCO	ECO & STD	0.61
BLONDE TOBACCO	ECO & STD	0.61
SIGNATURE TOBACCO	ECO & STD	0.61
CLASSIC MENTHOL	ECO & STD	0.87
FRESH MENTHOL	ECO & STD	0.87
GOLD	ECO & STD	0.52
SAPPHIRE	ECO & STD	0.87

COMPARATIVE AEROSOL HPHC ANALYSIS GLAS TEST ARTICLES AND COMBUSTIBLE CIGARETTES (3R4F AND MARLBORO GOLD BOX)

TABLE 4. BLONDE TOBACCO: Comparative Aerosol HPHC Analysis with 3R4F and Marlboro Gold Cigarette

BLONDE TOBACCO 50MG/ML	% Difference- Per day Basis				% Difference- Per day/mg Nicotine Basis			
	ECO Vs 3R4F	ECO Vs Marlboro	STD Vs 3R4F	STD Vs Marlboro Gold	ECO Vs 3R4F	ECO Vs Marlboro	STD Vs 3R4F	STD Vs Marlboro Gold
Anabasine	- 99.80%	NA	- 100.00%	NA	- 99.80%	NA	- 100.00%	NA
Normicotine	- 99.70%	NA	- 100.00%	NA	- 99.70%	NA	- 100.00%	NA
Acetaldehyde	- 99.98%	- 99.97%	- 99.98%	- 99.97%	- 99.98%	- 99.97%	- 99.99%	- 99.98%
Acrolein	- 99.98%	- 99.97%	- 99.97%	- 99.97%	- 99.98%	- 99.98%	- 99.98%	- 99.97%
Butanal	- 99.99%	NA	- 99.98%	NA	- 99.99%	- 99.99%	NA	- 99.99%
Crotonaldehyde	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%
Formaldehyde	- 99.61%	- 99.58%	- 99.32%	- 99.26%	- 99.61%	- 99.52%	- 99.52%	- 99.40%
Cadmium	- 99.98%	- 99.98%	- 99.98%	- 99.98%	- 99.98%	- 99.99%	- 99.99%	- 99.98%
Chromium	NA	- 96.54%	NA	- 97.26%	NA	- 96.04%	NA	- 97.79%
Lead	- 99.66%	- 99.71%	- 99.84%	- 99.86%	- 99.65%	- 99.67%	- 99.88%	- 99.89%
Nickel	NA	- 77.78%	NA	- 45.39%	NA	- 74.57%	NA	- 56.07%
Acrylonitrile	- 100.00%	- 99.99%	- 100.00%	- 99.99%	- 100.00%	- 99.99%	- 100.00%	- 100.00%
Benzene	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%
Propylene oxide	- 99.40%	NA	- 99.40%	- 99.40%	- 99.40%	- 99.58%	NA	NA
Toluene	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 100.00%	- 99.99%	- 99.99%

TABLE 5. BLUE TOBACCO: Comparative Aerosol HPHC Analysis with 3R4F and Marlboro Gold Cigarette

BLUE TOBACCO 50 MG/ML	% Difference-- Per day Basis				% Difference-- Per day/mg Nicotine Basis			
	ECO Vs 3R4F	ECO Vs Marlboro	STD Vs 3R4F	STD Vs Marlboro Gold	ECO Vs 3R4F	ECO Vs Marlboro	STD Vs 3R4F	STD Vs Marlboro Gold
Anabasine	- 99.80%	NA	- 100.00%	NA	- 99.80%	NA	- 100.00%	NA
Normicotine	- 99.70%	NA	- 100.00%	NA	- 99.69%	NA	- 100.00%	NA
Acetaldehyde	- 99.97%	- 99.96%	- 99.98%	- 99.97%	- 99.97%	- 99.96%	- 99.98%	- 99.97%
Acrolein	- 99.95%	- 99.95%	- 99.95%	- 99.94%	- 99.95%	- 99.96%	- 99.96%	- 99.95%
Butanal	- 99.99%	NA	- 99.99%	NA	- 99.99%	NA	- 100.00%	NA
Crotonaldehyde	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%
Formaldehyde	- 99.50%	- 99.45%	- 99.42%	- 99.36%	- 99.49%	- 99.37%	- 99.59%	- 99.49%
Cadmium	- 99.98%	- 99.98%	- 99.98%	- 99.98%	- 99.98%	- 99.98%	- 99.99%	- 99.99%
Chromium	NA	- 96.53%	NA	- 73.20%	NA	- 96.03%	NA	- 78.44%
Lead	- 99.66%	- 99.71%	- 99.86%	- 99.87%	- 99.65%	- 99.67%	- 97.08%	- 97.24%
Nickel	NA	- 77.74%	NA	- 9.02%	NA	- 74.52%	NA	- 26.82%
Acrylonitrile	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 100.00%	- 100.00%
Benzene	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%
Propylene oxide	- 99.35%	NA	- 99.35%	NA	- 99.34%	NA	- 99.54%	NA
Toluene	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%

TABLE 6. CLASSIC MENTHOL: Comparative Aerosol HPHC Analysis with 3R4F and Marlboro Gold Cigarette

CLASSIC MENTHOL 50 MG/ML	% Difference – Per Day Basis				% Difference – Per Day per mg Nicotine Basis			
	ECO Vs 3R4F	ECO Vs Marlboro	STD Vs 3R4F	STD Vs Marlboro Gold	ECO Vs 3R4F	ECO Vs Marlboro	STD Vs 3R4F	STD Vs Marlboro Gold
Anabasine	- 99.73%	NA	- 100.00%	NA	- 99.73%	NA	- 100.00%	NA
Normicotine	- 98.96%	NA	- 100.00%	NA	- 98.95%	NA	- 100.00%	NA
Acetaldehyde	- 99.96%	- 99.95%	- 99.96%	- 99.95%	- 99.96%	- 99.94%	- 99.97%	- 99.96%
Acrolein	- 99.97%	- 99.96%	- 99.96%	- 99.97%	- 99.97%	- 99.96%	- 99.97%	- 99.97%
Butanal	- 99.99%	NA	- 99.99%	NA	- 99.99%	NA	- 99.99%	NA
Crotonaldehyde	- 99.99%	- 99.98%	- 99.99%	- 99.98%	- 99.99%	- 99.98%	- 99.99%	- 99.99%
Formaldehyde	- 99.47%	- 99.42%	- 99.66%	- 99.63%	- 99.46%	- 99.34%	- 99.76%	- 99.70%
Cadmium	- 99.97%	- 99.97%	- 99.97%	- 99.97%	- 99.97%	- 99.98%	- 99.98%	- 99.98%
Chromium	NA	- 95.09%	NA	- 95.47%	NA	- 94.38%	NA	- 96.35%
Lead	- 99.51%	- 99.59%	- 97.74%	- 98.12%	- 99.51%	- 99.53%	- 98.40%	- 98.49%
Nickel	NA	- 68.45%	NA	- 13.57%	NA	- 63.50%	NA	- 30.47%
Acrylonitrile	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%
Benzene	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%
Propylene oxide	- 99.06%	NA	- 99.06%	NA	- 99.05%	NA	- 99.33%	NA
Toluene	- 99.89%	- 99.88%	- 99.99%	- 99.99%	- 99.89%	- 99.86%	- 99.99%	- 99.99%

TABLE 7. FRESH MENTHOL: Comparative Aerosol HPHC Analysis with 3R4F and Marlboro Gold Cigarette

FRESH MENTHOL 50MG/ML	% Difference- Per day Basis				% Difference- Per day/mg Nicotine Basis			
	ECO Vs 3R4F	ECO Vs Marlboro	STD Vs 3R4F	STD Vs Marlboro Gold	ECO Vs 3R4F	ECO Vs Marlboro	STD Vs 3R4F	STD Vs Marlboro Gold
Anabasine	- 99.72%	NA	- 100.00%	NA	- 99.71%	NA	- 100.00%	NA
Normicotine	- 99.51%	NA	- 100.00%	NA	- 99.51%	NA	- 100.00%	NA
Acetaldehyde	- 99.97%	- 99.95%	- 99.97%	- 99.96%	- 99.97%	- 99.95%	- 99.98%	- 99.96%
Acrolein	- 99.95%	- 99.95%	- 99.95%	- 99.95%	- 99.95%	- 99.94%	- 99.97%	- 99.96%
Butanal	- 99.99%	NA	- 99.98%	NA	- 99.99%	NA	- 99.99%	NA
Crotonaldehyde	- 99.99%	- 99.98%	- 99.99%	- 99.98%	- 99.99%	- 99.98%	- 99.99%	- 99.99%
Formaldehyde	- 99.36%	- 99.30%	- 99.47%	- 99.42%	- 99.36%	- 99.20%	- 99.63%	- 99.54%
Cadmium	- 99.97%	- 99.97%	- 99.98%	- 99.98%	- 99.97%	- 99.97%	- 99.98%	- 99.98%
Chromium	NA	- 95.07%	NA	- 80.84%	NA	- 94.36%	NA	- 84.59%
Lead	- 99.51%	- 99.59%	- 98.90%	- 99.08%	- 99.51%	- 99.53%	- 99.22%	- 99.26%
Nickel	NA	- 68.32%	NA	- 23.44%	NA	- 63.75%	NA	- 38.42%
Acrylonitrile	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%
Benzene	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%
Propylene oxide	- 98.50%	NA	- 99.12%	NA	- 98.49%	NA	- 99.38%	NA
Toluene	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.98%	- 99.99%	- 99.99%

TABLE 8.: GOLD: Comparative Aerosol HPHC Analysis with 3R4F and Marlboro Gold Cigarette

GOLD 50 MG/ML	% Difference – Par Day Basis				% Difference – Par Day per mg Nicotine Basis			
	ECO Vs 3R4F	ECO Vs Marlboro	STD Vs 3R4F	STD Vs Marlboro Gold	ECO Vs 3R4F	ECO Vs Marlboro	STD Vs 3R4F	STD Vs Marlboro Gold
Anabasine	- 99.83%	NA	- 100.00%	NA	- 99.83%	NA	- 100.00%	NA
Normicotine	- 99.75%	NA	- 100.00%	NA	- 99.74%	NA	- 100.00%	NA
Acetaldehyde	- 99.97%	- 99.96%	- 99.98%	- 99.97%	- 99.97%	- 99.96%	- 99.98%	- 99.97%
Acrolein	- 99.92%	- 99.92%	- 99.95%	- 99.95%	- 99.92%	- 99.91%	- 99.96%	- 99.96%
Butanal	- 99.99%	NA	- 99.99%	NA	- 99.99%	NA	- 100.00%	NA
Crotonaldehyde	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%
Formaldehyde	- 99.40%	- 99.35%	- 99.58%	- 99.54%	- 99.40%	- 99.25%	- 99.70%	- 99.63%
Cadmium	- 99.98%	- 99.98%	- 99.98%	- 99.98%	- 99.98%	- 99.98%	- 99.99%	- 99.98%
Chromium	NA	- 97.05%	NA	- 51.58%	NA	- 97.05%	NA	- 51.55%
Lead	- 99.71%	- 99.76%	- 99.77%	- 99.81%	- 99.70%	- 99.72%	- 99.84%	- 99.84%
Nickel	NA	- 81.07%	NA	- 12.24%	NA	- 78.34%	NA	- 29.41%
Acrylonitrile	- 100.00%	- 99.99%	- 100.00%	- 99.99%	- 100.00%	- 99.99%	- 100.00%	- 100.00%
Benzene	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%
Propylene oxide	- 99.45%	NA	- 99.45%	NA	- 99.44%	NA	- 99.61%	NA
Toluene	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 100.00%	- 99.99%

TABLE 9. SAPPHIRE: Comparative Aerosol HPHC Analysis with 3R4F and Marlboro Gold Cigarette

SAPPHIRE 50MG/ML	% Difference- Per day Basis				% Difference- Per day/mg Nicotine Basis			
	ECO Vs 3R4F	ECO Vs Marlboro	STD Vs 3R4F	STD Vs Marlboro Gold	ECO Vs 3R4F	ECO Vs Marlboro	STD Vs 3R4F	STD Vs Marlboro Gold
Anabasine	-99.72%	NA	- 100.00%	NA	- 99.72%	NA	- 100.00%	NA
Normicotine	- 98.97%	NA	- 100.00%	NA	- 98.96%	NA	- 100.00%	NA
Acetaldehyde	- 99.89%	- 99.85%	- 99.98%	- 99.97%	- 99.89%	- 99.83%	- 99.98%	- 99.98%
Acrolein	- 99.75%	- 99.74%	- 99.92%	- 99.92%	- 99.75%	- 99.70%	- 99.94%	- 99.93%
Butanal	- 99.99%	NA	- 99.99%	NA	- 99.99%	NA	- 99.99%	NA
Crotonaldehyde	- 99.99%	- 99.98%	- 99.99%	- 99.98%	- 99.99%	- 99.98%	- 99.99%	- 99.99%
Formaldehyde	- 95.90%	- 95.52%	- 99.68%	- 99.65%	- 95.87%	- 94.88%	- 99.77%	- 99.72%
Cadmium	- 99.97%	- 99.97%	- 99.99%	- 99.99%	- 99.97%	- 99.97%	- 99.99%	- 99.99%
Chromium	NA	- 95.07%	NA	- 94.62%	NA	- 94.36%	NA	- 95.67%
Lead	- 99.51%	- 99.59%	- 99.63%	- 99.62%	- 99.51%	- 99.53%	- 99.74%	- 99.75%
Nickel	NA	- 63.32%	NA	- 24.33%	NA	- 63.75%	NA	- 39.13%
Acetonitrile	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%	- 99.99%
Benzene	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%	- 100.00%
Propylene oxide	- 99.07%	NA	- 99.07%	NA	- 99.06%	NA	- 99.34%	NA
Toluene	- 99.98%	- 99.98%	- 99.99%	- 99.99%	- 99.98%	- 99.98%	- 99.99%	- 99.99%