Comparison of toxicant levels in mainstream aerosols generated by Ruyan® electronic nicotine delivery systems (ENDS) and conventional cigarette products

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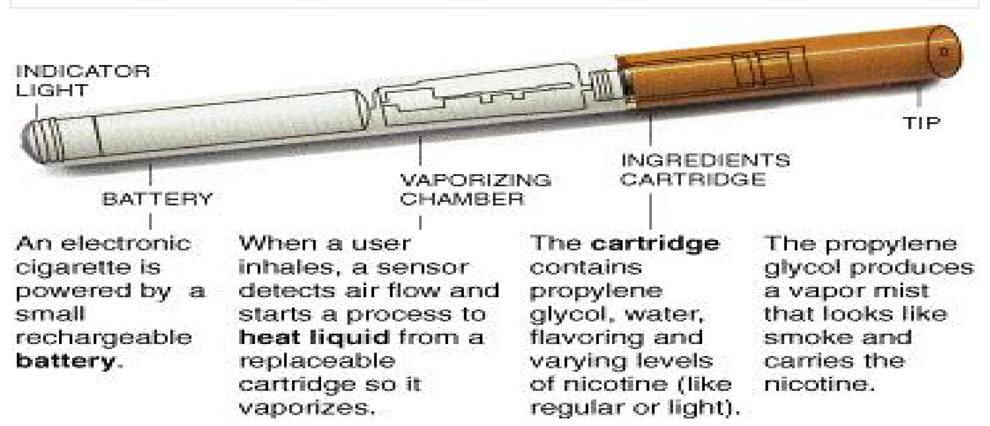
Abstract

Rationale: To determine whether claims of reduced emissions from a smokeless electronic cigarette (electronic nicotine delivery system, aka ENDS) were justified. Scope: The Ruyan® classic V8 electronic cigarette ("ENDS") was tested against a very low tar (1.2 mg yield) cigarette ("VLTC") and compared with published emissions for the US-style of Marlboro KS cigarettes. Procedures: Products were smoke according to the ISO standard (35 mL puff, 2 s puff duration, 60 s puff interval), and the resulting mainstream aerosols analyzed for 62 cigarette smoke toxicants by Labstat International and British American Tobacco, as per their library of methods. Data: The Ruyan® cartridge yielded over 300 puffs of aerosol (10.5 L, mean TPM weight 0.88 mg) comprising 82% propylene glycol, 15% water, 1% nicotine, 2% unidentified particulate matter and flavors. Of 62 cigarette-smoke toxicants 37 were measurable in VLTC smoke and 11 in Ruyan® vapor. Estimated relative toxicant emissions scores, adjusted for nicotine, were 0.4 for Ruyan; 55 for VLTC; and 137 for Marlboro KS. Three tobacco-specific nitrosamines in Ruyan® vapor were present at trace levels no greater than for medicinal nicotine; mercury was present at trace level. Ruyan®, VLTC, and Marlboro regular cigarettes yielded 9 µg, 23 µg, and 101 µg mean nicotine, respectively, per 35 mL puff. Conclusion: The Ruyan® aerosol as determined under ISO conditions for cigarettes is free of most toxicants found in cigarette smoke; and those measurable are in very low concentration. ENDS products are subject to frequent modifications and should be retested at periodic interval using machine smoking parameters that replicate actual human puffing behavior instead of those in the ISO standard.

Introduction

The history of ENDS is often reported to have begun with the invention of the electronic cigarette in 2003 by Hon Lik of Golden Dragon Holdings of Beijing, China, (U.S. Patent 7,832,410, 2010) and that invention was the basis for the Ruyan® brand of ENDS. However, H. A. Gilbert of Beaver Falls, PA, received U.S. Patent 3,200,819 in 1965 for a battery-powered nontobacco cigarette. There has also been the heavily researched, tobacco-containing, electrically heated cigarette smoking system ("EHCSS") marketed under the brand name Accord®. All products function by electrically heating a medium capable of forming an aerosol to a sufficient temperature that an inhalable aerosol can be formed and inhaled by the user when a puff is taken on the device. A diagram of a typical ENDS is shown below.



There are numerous varieties of ENDS available on the US market. Some have dimensions similar to a commercial cigarette, but many are larger both in terms of length and diameter. Differences in the amounts and/or compositions of the mainstream aerosol delivered to a user depend on several factors in addition to the composition of the fluid used to generate the aerosol. These include type of battery and remaining charge on it, the electronic control system, the dimensions of the air passages, the nature of the cartomizer (atomizer), and how the user puffs on the device. Unlike factory-made cigarettes, some brands of ENDS have components that can be interchanged with those of other brands to give modified products ("Mods") that may give higher nicotine yields.

Experimental

There is no internationally- or FDA-accepted standard for the puffing of ENDS to determine the amount of mainstream aerosol ("MSA") produced from an ENDS and/or the chemical and toxicological properties of the aerosol. However, several approaches have been reported, including using puffing on ENDS with manual syringes, as well as, automated smoking machines. It is important to use an automated smoking machine that meets the requirements of ISO 3308:2000 (Routine analytical cigarette-smoking machine — Definitions and standard conditions) to ensure that the puffing parameters are repeatable, to ensure that the machine can maintain puff profiles when puffing on ENDS with high pressure drop (resistance to draw), and facilitate the measurement of components in the gas-vapor phase ("GVP") of the MSA generated when puffing on an ENDS. While no one smoking protocol can replicate the manner in which smokers puff conventional cigarettes and/or ENDS, the ISO standard puffing regimen is often used in addition to more intense smoking regimens.

The test product was the Ruyan® V8 Classic with 16 mg-nicotine-labeled cartridges, manufactured and supplied from Ruyan's Tianjin, China factory, and tested in 2009. Batteries were recharged before testing, and fresh cartridges used. A United States blend very low tar (1.2 mg yield) cigarette ("VLTC") – was the main comparator. The analytical data presented were provided at no cost by British American Tobacco (BAT) Group Research and Development, Southampton, UK The reporting limit ("RL" in the Table) is the mean limit of quantification per VLTC based on five VLTCs smoked. The BAT methods were used (available through the Library web page at http://www.bat-science.com).

Results & Discussion

The Table below shows comparisons of ISO smoke results from the Ruyan® (20 to 50 puffs depending on method), a VLTC, and published data on Marlboro KS (Counts *et al.*, ***Regulatory Toxicology & Pharmacology*** 2005; 41(3):185-227).

Test Piece		Ruyan® (16 mg)	VLTC	Marlboro FF KS
Analytes	**Units**			
Nicotine	mg	0.06	0.16	1.02
CO	mg	<RL	1.6	12.9
Acetaldehyde	µg	1.39	75.7	601
Formaldehyde	µg	0.37	1.79	119
Acrolein	µg	<RL	3.84	33.0
o-cresol	µg	<RL	0.59	4.07
m+p Cresols	µg	<RL	1.78	11.2
Benzo[a]pyrene	ng	<RL	1.13	11.9
Hydrogen cyanide	µg	<RL	6.08	194
1,3-butadiene	µg	<RL	<RL	50.8
Acrylonitrile	µg	<RL	<RL	10.0
Benzene	µg	<RL	<RL	45.2
NNN	ng	0.14	26.3	157
NNK	ng	0.17	11.4	108
NAT	ng	0.14	27.2	140
NAB	ng	<RL	2.86	26.6

The data in the Table above is a snapshot of the larger dataset (over 60 analytes) that has been obtained on the Ruyan® aerosol and the VLTC mainstream smoke. Most of the analytes (aka smoke toxicants) shown in the Table were present in mainstream aerosol from the Ruyan® at concentrations below the RL for the methods used. These analytes included acrolein, acrylonitrile, benzene, benzo(a)pyrene, 1,3-butadiene, the three cresols, hydrogen cyanide, and carbon monoxide, and thus are near 100% reductions versus a conventional full-flavor KS cigarette (e.g., data on Marlboro FF KS as reported by Counts *et al.*, 2005). Similarly, the analytes from the Ruyan® aerosol at concentrations above the RL (acetaldehyde, formaldehyde, TSNAs were reduced by more than 90% when compared with the concentrations in the mainstream smoke from the conventional full-flavor cigarette. No diethylene glycol ("DEG") was detected in the Ruyan® aerosol. It is expected that more frequent and more intense puffing on the Ruyan® ENDS will have little or no absolute effect on the toxicants in the aerosol because they are present at such low levels.