67 *HOW SAFE IS AN E-CIGARETTE?*

THE RESULTS OF INDEPENDENT CHEMICAL AND MICROBIOLOGICAL ANALYSIS 1

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Conflict of Interest and Disclosure statement

This work is part of a research contract between the Health New Zealand Ltd and Ruyan Group Holdings, Beijing.

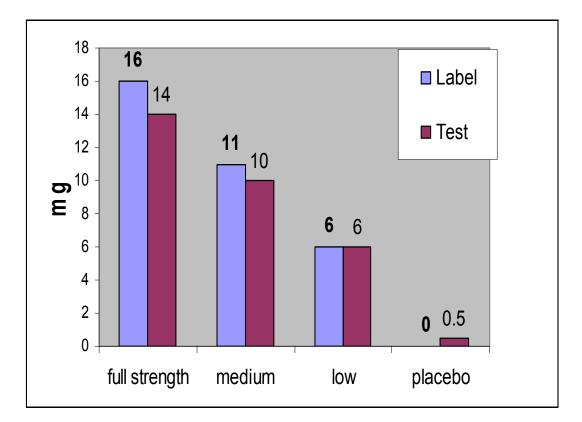
No financial benefit accrues and no Ruyan stock is held by Health New Zealand Ltd or the author

> The research was planned by Health New Zealand Ltd

Ruyan have not placed any bar on publication

Results of all completed tests have been disclosed.

Nicotine Content of the The Ruyan cartridge



Conclusion

• The labeling is similar to actual content.

• Batch to batch and within-batch

variations were not studied.

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Risk of microorganisms in cartridge liquid

Samples:	One unused cartridge
	One repeatedly used cartridge

Tests:

cfu/mL

Aerobic plate count 35 °C	<10
Anaerobic	<10
Legionella	<10

Conclusion

<mark>No tendency for microorganisms to</mark> grow in the liquid

Laboratory: ESR, a Crown Research Institute, Porirua, NZ.

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Metalsmg/Kg (ppm)Samples: Liquid in unused cartridges

Sb (antimony)	<1
As	< 0.1
Cd	< 0.01
Cr	< 0.2
Co	< 0.5
Cu	< 0.3
Pb	< 0.1
Mn	< 0.1
Ni	< 0.2

Conclusion:

Metals all < 1 ppm: Not a risk

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Is this a tobacco product? Test samples: with and without nicotine

Fragrance/odour	Yes	
Tobacco -specific		
Nitrosamines	8 ppb (ng/g)	
For comparison		
NRT gum ¹	8 ng/g)	
Unburnt cig. Tobacc	1200 ng/g	
Cigarette smoke ³	to 500 ng /cigarette	

MAO inhibition:Of MAO Ano sig. effectOf MAO Bno sig. effect

- 1. Stepanov I, Jensen J, Hatsukami D, Hecht SS. Tobacco-specific nitrosamines in new tobacco products. Nicotine Tobacco Research 2006; 8: 309-313.
- 2. TSNAs in NZ cigarette tobaccos <u>www.smokeless.org.nz/snuffregulations.htm</u> at Table 2.
- **3.** Counts ME, Morton MJ, Laffoon SW, *et al.* Smoke composition and predicting relationships for international commercial cigarettes smoked with three machine smoking test mode. *Regulatory Toxicol Pharmacol* 2005;**41**:185–227.

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Volatile smoke toxicants (VOCs)

Toxicant (LOQ=0.3 ppm)	Concentration in blank (parts per million; ppm)	Concentration in headspace of cartridge: parts per million; ppm
Acetaldehyde	<loq< td=""><td>9.40</td></loq<>	9.40
Benzene	<loq< td=""><td>1.50</td></loq<>	1.50
Acrolein	<loq< td=""><td>1.30</td></loq<>	1.30
Cresols (total m-, o- and p-)	<loq< td=""><td>0.49</td></loq<>	0.49
1,3-Butadiene	<loq< td=""><td><loq< td=""></loq<></td></loq<>	<loq< td=""></loq<>
Hydrogen cyanide	<loq< td=""><td><loq< td=""></loq<></td></loq<>	<loq< td=""></loq<>
Acrylonitrile	<loq< td=""><td><loq< td=""></loq<></td></loq<>	<loq< td=""></loq<>
Propylene oxide	<loq< td=""><td><loq< td=""></loq<></td></loq<>	<loq< td=""></loq<>
Diethylene oxide	<loq< td=""><td><loq< td=""></loq<></td></loq<>	<loq< td=""></loq<>

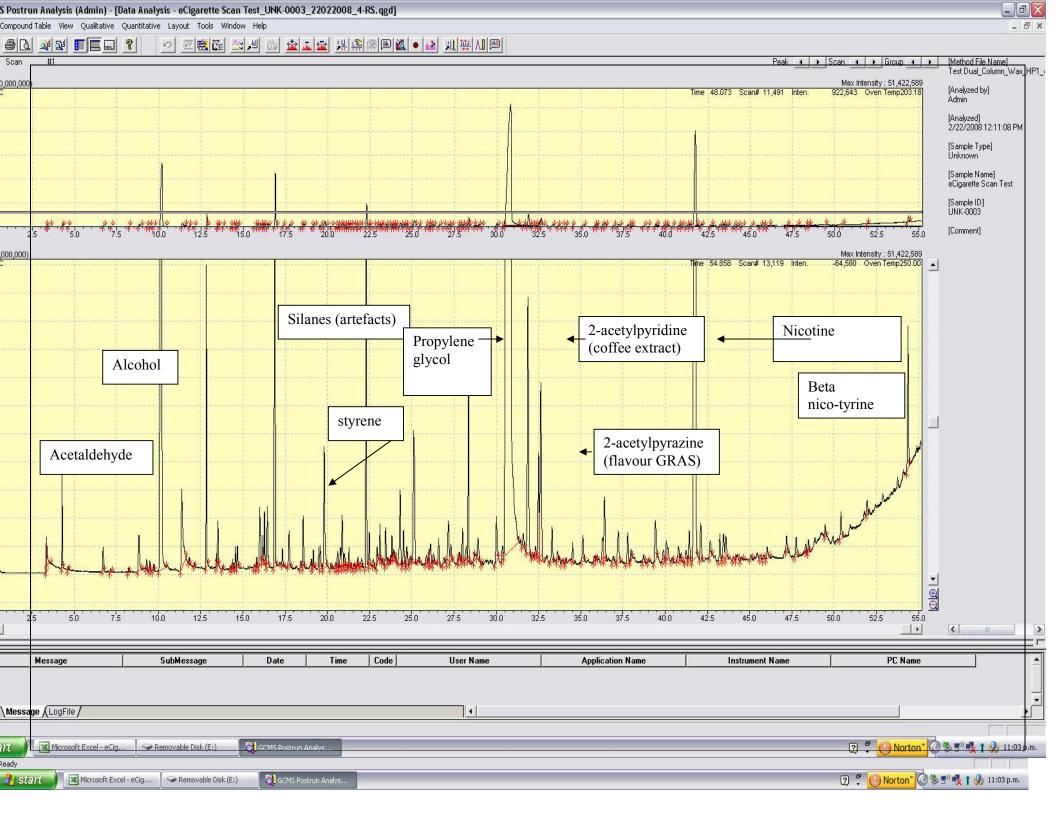
SIFT-MS headspace analysis of the Ruyan e-Cigarette cartridge (mean of two replicates).

To convert from ppm at 25degC to mg/m3 or to ug/ml =ppm x MW/24.45

Due to interference in ion measurements from alcohol:

- VOCs detected as > LOQ should be verified by GC-MS type methods.
- Values are upper limits

In the e-cigarette, smoke toxicants such as HCN, Butadiene and acrylonitrile are below 0.3 ppm



Further VOCs detected in head space of e-cigarette cartridge liquid by HS-SPME

(Headspace Scan/Solid Phase MicroExtraction)

Acetone	0.5 to 1 ppm minimum
Styrene	0.5 to 1 ppm minimum
Xylene	0.5 to 1 ppm minimum

After drawback on the e-cigarette, the vapourised mist needs to be measured by GC-MS to allow for the higher temperature during vapourisation.

Inhalation safety levels for acetaldehyde

Concentration in cartridge headspace: 9.5 ppm

OSHA permits concentrations of 100 ppm (average) for workplace air across one 8-hour shift, 40 hours per week, for 1 year duration or more.

If the e-cigarette smoker smoked one cartridge (300 breaths) during one 8-hour shift, e-cigarette smoking would comprise 5% of workplace breaths taken.

Thus if a workplace was acetaldehyde-free to begin with, the e-cigarette smoker would have to inhale vapour with a concentration of 2000 ppm to equal what OSHA permits for average workplace air levels.

This is 200 times the 9.5 ppm measured by SIFT-MS in the headspace of the Ruyan cartridge.

- Acetaldehyde should be re-measured in the mist inhaled from the drawback.
- Better, the source of the acetaldehyde in the cartridge liquid should be detected and eliminated if at all possible.

Carcinogens, non-volatile

Samples: cartridge liquid, not head space

TSNAs (nitrosamines) 8 ng / cartridge as above

BENZO ALPHA PYRENE <1 ng / cartridge (< LOD)

- In an inhaler, the non-volatile compounds are not likely to be inhaled.
- However the e-cigarette relies on a higher temperature to vapourise nicotine
- A scan of the vapourised mist from the ecigarette is required to check what else has been vapourised.
- Fowles J and Dybing E. Application of toxicological risk assessment principles to the chemical constituents of cigarette smoke. Tob Control 12 (4): 424. Web-only table from EPA California. <u>http://tobaccocontrol.bmj.com/cgi/data/12/4/424/DC1/1</u>

Risk of contamination from mouthpiece

Risk:

Meningococcal meningitis, tuberculosis.

Public health advice is to avoid sharing glasses and cigarettes.

Sharing the e-cigarette mouthpiece is

inadvisable.

The risk is largely eliminated by separate mouth pieces for different users.

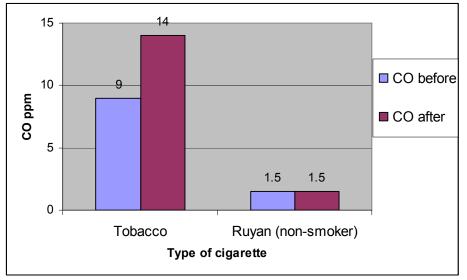
(The black mouthpiece is detachable from the white nicotine-containing cartridge.)

Safety of e-cigarette 'smoke' for bystanders

The 'smoke' is propylene glycol – virtually non-

toxic, does not contain gases of combustion.

Carbon monoxide in exhaled breath, before and after the first cigarette of the day



- CO is a marker gas for combustion.
- The e-cigarette does not increase CO in breath.
- Smoking the e-cigarette would not be restricted The NZ Smoke-free Environments Act only restricts tobacco and marijuana smoke.

The e-cigarette reduces second-hand smoke

1) by replacing the lighting up of tobacco, and

2) by not producing second-hand smoke itself.