

Electronic Cigarettes (e-cigarettes)

What are electronic cigarettes?

Electronic cigarettes, also known as e-cigarettes, are battery-operated devices that have cartridges with liquid chemicals in them.

Heat from a battery powered atomizer turns the chemicals into a vapour that is inhaled by the user (called vaping). E-cigarettes look like regular cigarettes. There are other electronic smoking products that look like cigars and pipes.

Some e-cigarettes are reusable. The cartridges of reusable e-cigarettes can be replaced or re-filled with liquid (sold separately). The bottled liquid is often called e-liquid. Reusable e-cigarette kits include a battery charger. You can also buy disposable e-cigarettes.

What is in e-cigarette liquid?

There are no standards or labelling requirements for e-cigarettes. This makes it hard to know exactly what is in the liquid. Common contents include a mix of water and propylene glycol, a man-made product used in antifreeze and theatre fog. Many e-cigarettes also have chemicals in them that give the vapour a flavour. Tests of some of the products labelled as "nicotine-free" have found nicotine in them.

Are they safe?

Although e-cigarettes are promoted as being safe, they haven't been tested for safety. There are no quality controls for making e-cigarettes.

Because chemicals in the cartridges vary, it's hard to know what e-cigarette users and people nearby are breathing in. Promotional materials for e-cigarettes describe the vapour as water vapour. However, the U.S. Food and Drug Administration found cancercausing chemicals in some of the cartridges.

Propylene glycol is one of the common ingredients in e-cigarette cartridges. Propylene glycol is used as a food preservative and as antifreeze. It's not known if vapourized propylene glycol or other chemicals in the cartridges are safe to inhale.

Given that e-cigarettes don't seem to create the 7,000 chemicals (69 of which are known to cause cancer) found in cigarette smoke, they are likely safer than smoking a regular cigarette; however, that doesn't mean they are safe to use.

In one of the few studies done on the use of e-cigarettes, researchers found signs of the airways becoming narrow and inflammed after using the e-cigarette for only 5 minutes.

Health Canada advises not to use e-cigarettes because they haven't been tested and may be harmful. They also warn e-cigarettes may cause nicotine poisoning and addiction. Health Canada reminds people to keep the products away from children to prevent nicotine poisoning and choking.



AlbertaQuits

AlbertaQuits.ca

Call toll-free 1-866-710-7848 (QUIT)



Electronic Cigarettes (e-cigarettes)

Are they legal?

E-cigarettes and e-liquids that contain nicotine or that are promoted with a therapeutic health claim (for example, that they help people quit smoking) are regulated health products which require Health Canada authorization before they can legally be sold in Canada. To date, no products have received authorization.

Please call Health Canada toll-free at 1-800-267-9675 if you would like more information about the regulation of e-cigarettes and e-liquids.

Can they be smoked anywhere, anytime?

There is a growing trend to ban smoking e-cigarettes indoors. Many health organizations support a ban on the sale of e-cigarettes until more research on the health effects is done.

E-cigarettes may not be used indoors at Alberta Health Services (AHS) sites until there is more information about their safety. E-cigarettes may be used outdoors on AHS property only at the risk of the user.

Do e-cigarettes help people quit smoking?

There is no evidence that using e-cigarettes help people quit smoking. Health Canada, the U.S. Food and Drug Administration, and the World Health Organization don't support e-cigarettes as stop-smoking products.

Health Canada has approved stop-smoking medicine, including over-the-counter nicotine patches, gum, lozenges, and the inhaler. Prescription medicine is also available. These products have been proven to be safe and to help tobacco users reduce or quit.

Alberta Health Services *AlbertaQuits*.ca gives support and information for people interested in quitting smoking. Call or text 1-866-710-7848 (QUIT) or visit www.albertaquits.ca.

More information on e-cigarettes, including the sources of the information in this document, can be found at www.albertaquits.ca.

For more information, please contact Alberta Health Services Tobacco Reduction Program at tru@albertahealthservices.ca or phone 780-422-1350 (Edmonton).

There is a category of "smoking" products known as electronic smoking products (ESPs). These products are also referred to as electronic nicotine delivery systems (ENDS) and, more commonly, electronic cigarettes or e-cigarettes.

Electronic Smoking Products (ESPs) consist of a cartridge that stores a liquid solution, a batteryoperated heating element and an atomizer that, when heated, slowly vaporizes the contents of the cartridge for inhalation.¹

The cartridges of most products can be replaced or re-filled with liquid, known as e-liquid, or e-juice, that is sold separately. The bottled liquid is referred to as e-liquid. E-liquid is available with and without nicotine. Disposable ESPs are also available.

A variety of flavours of e-liquid solutions are available. Some of the flavours are identified with particular tobacco name brands (like Marlboro); while others, such as menthol, are commonly associated with conventional tobacco products. Additional flavours such as chocolate and strawberry are likely to appeal to younger users and may undermine recent Canadian legislation to ban many flavours in most tobacco products. The flavoured solutions may also contribute to the use of e-cigarettes as a gateway to smoking cigarettes.

The United States Food and Drug Administration (FDA) warns that e-cigarettes can increase nicotine addiction among young people and is concerned that the use of e-cigarettes may lead young people to experiment with conventional tobacco products.²

Promotional material describes the use of these products as safe. However, these products have not been adequately tested for consumer use and the short- and long-term impact of using these products is unknown. The unproven claims of safety made by many manufacturers may be a contributing factor to the rise in popularity of these products.



Research is confirming that ESPs are not emission-free and the vapour could affect the health of users and those around them. In particular, ultrafine particles formed from supersaturated 1,2-propanediol vapor can be deposited in the lung, and aerosolized nicotine seems capable of increasing the release of the inflammatory signaling molecule NO upon inhalation.¹⁹ Signs of airway constriction and inflammation are evident after only five minutes of use³, confirming the need for further testing of these products²¹.

Health Canada and Alberta Health Services (AHS) advises Canadians not to purchase or use ESPs because these products may pose health risks and have not been fully evaluated for safety, quality and efficacy.⁴

The FDA Center for Drug Evaluation, Division of Pharmaceutical Analysis has conducted tests on ESPs and concludes that quality-control processes used to manufacture e-cigarettes are substandard or non-existent⁵ and the concentrations of nicotine and other chemicals in the cartridges vary.

Testing conducted by the FDA found that e-cigarette cartridges labelled as nicotine-free contained nicotine and that three different electronic cigarette cartridges with the same label produced markedly different amounts of nicotine with each puff. Some studies show that e-cigarettes can deliver substantial and even toxic amounts of nicotine⁶ and other chemicals.



For more information

AlbertaQuits.ca

Call toll-free 1-866-710-QUIT (7848)

Testing also revealed that the products contained detectable levels of carcinogens and toxic chemicals. Tobacco-specific constituents suspected of being harmful to humans—anabasine, myosmine and β-nicotyrine—were detected in most of the samples tested.⁷ FDA research also indicates that diethylene glycol was detected in one cartridge at approximately 1%. Diethylene glycol, an ingredient used in antifreeze, is toxic to humans.⁸ Health Canada testing indicates that propylene glycol (also used in antifreeze) is a constituent in at least some of the liquid solutions.⁹

The Health Canada advisory on ESPs states that "nicotine is a highly addictive and toxic substance, and the inhalation of propylene glycol is a known irritant." Health Canada further advises that ESPs may pose risks, such as nicotine poisoning and addiction, and recommends that the electronic products and cartridges be kept out of the reach of children to prevent potential choking incidents or nicotine poisoning.¹⁰ Media from Israel have reported that a young child died after the ingestion of e-cigarette nicotine. There is sufficient evidence to caution children and adolescents, pregnant women, and women of reproductive age about using ESPs. Fetal and adolescent nicotine exposure can have long-term consequences for brain development.21

The limited research that has been conducted on ESPs is impeded by the void of regulatory requirements for product design and content, which means test results may not be applicable beyond the individual products tested.¹¹

Because of the variability among products, the FDA cautions that their analysis should not be used to draw conclusions about what substances are or are not present in particular e-cigarettes or brands of e-cigarettes.¹²

E-cigarettes are promoted as a "smoke-like" alternative to smoking in places where smoking is prohibited. Evidence about the safety or health effects of exposure to ESP vapour is not available. Some manufacturers of ESPs suggest using e-cigarettes with low levels of nicotine or using gradually tapered down nicotine levels as a method of reducing or quitting smoking. Some promotional materials for ESPs misleadingly claim that the World Health Organization (WHO) supports the use of ESPs as cessation aids. The WHO states that the e-cigarette is not a proven nicotine replacement therapy and has requested that marketers "immediately remove from their websites and other informational materials any suggestion that WHO considers it to be a safe and effective smoking cessation aid."¹³

Health Canada, AHS and the FDA also do not support the use of ESPs as cessation aids.

Tobacco cessation aids, including over-the-counter nicotine replacement therapy in the form of nicotine patches, gum and lozenges or prescription medications (bupropion¹⁴ and varenicline¹⁵) that have been clinically tested and approved by Health Canada are available to help tobacco users reduce or quit smoking.

Health Canada has also approved nicotine inhalers as smoking cessation aids. Nicotine inhalers consist of a small, white, plastic tube with a cartridge that contains a clearly identified amount of nicotine. Nicotine inhalers are designed to be "puffed" and not actually inhaled; the nicotine is absorbed by the cells in the mouth.

When e-cigarettes are used as cessations aids, they are intended to deliver nicotine directly to the lungs. None of the approved, regulated cessation aids such as nicotine patches and chewing-gum delivers nicotine to the lungs. The effects of the delivery of nicotine to the lungs are unknown and potentially dangerous."¹⁶ In one instance, a woman developed lipid pneumonia after using e-cigarettes. The pneumonia cleared up when she stopped using e-cigarettes.¹⁷

E-cigarettes may facilitate tobacco addiction when used to provide a dose of nicotine in places where traditional cigarette use is not permitted. Several major tobacco companies have launched e-cigarette brands, including North America's largest tobacco manufacturer, Philip Morris.

The American Association of Public Health Physicians supports the sale of ESPs to adults and recommends that minors should not be permitted to purchase the products. AHS supports the development of government policy that would restrict the use of ESPs in public places, restrict the flavouring of these products, and prohibit the sale of ESPs to minors.

The FDA is in the process of establishing regulations for ESPs. Although some ESPs, including those made by tobacco companies, have health warnings listed on the packages, these warnings have not been created, regulated or standardised by the FDA.²²

The American Cancer Society, American Heart Association, American Lung Association, Action on Smoking and Health (U.S.), Campaign for Tobacco-Free Kids, Americans for Nonsmokers' Rights and the Association for the Treatment of Tobacco Use and Dependence support restrictions on e-cigarettes.

Several countries prohibit the sale of e-cigarettes. There is a growing number of jurisdictions that prohibit the indoor use of e-cigarettes and the sale of the products to minors. In October 2014, the Wold Health Organization (WHO) developed a report on Electronic Nicotine Delivery Systems.²¹ In this report the WHO recomends several regulatory restrictions for ESPs including:

- The limitation of promotion and advertising to reduce the uptake and use by non smokers, pregnant women and youth.
- Limit the ability of manufacturers to minimize potential health risks to ESP users and non-users and to prohibit unproven health claims.²¹

More information on restrictions on the use and sale of electronic smoking products can be found in the Global Advisors Smokefree Policy (GASP) white paper on electronic cigarettes, which is available at *http://www.njgasp.org/E-Cigs_White_Paper.pdf*

Misleading claims on the websites of some of the ESP manufacturers imply that the products have market authorization in Canada. ESPs that do not include nicotine are not required to be regulated under Canada's Food and Drug Act, which is accurate. However, no ESPs have been granted market authorization in Canada, regardless of whether or not they contain nicotine. Detailed information from Health Canada that clarifies regulations regarding the sale and importation of ESPs is presented at the end of this document.

At a minimum, more research is required to inform potential regulatory options. More research is needed on the composition of refill liquids and of vapour, toxicology, carcinogenicity, effects of long-term use and exposure, addictive potential, abuse liability, risks of nicotine refill bottles, adverse effects, and efficacy for smoking behaviour (cessation and reduction) in comparison with nicotine replacement therapy (NRT).¹⁸

The use of ESPs in AHS facilities or on AHS property is not permitted, is not recommended nor will these products be endorsed by AHS as effective smoking cessation aids.

Complaints involving ESPs can be reported to the Health Products and Food Branch Inspectorate by calling the toll-free hotline at 1-800-267-9675 or by writing to

Health Products and Food Branch Inspectorate Health Canada Address Locator: 2003C Ottawa, Ontario K1A 0K9

To access evidence-based information and support to quit smoking, call Alberta Health Services AlbertaQuits Helpline (1-866-710-7848(QUIT)—a free, confidential counselling telephone service, whereby callers can access help developing an individual quit plan, receive information or be referred to services available in their community.

The Therapeutic Products Directorate (TPD) of Health Canada is the Canadian federal authority that regulates pharmaceutical drugs and medical devices for human use. Prior to being given market authorization, a manufacturer must submit substantive scientific evidence of a product's safety, efficacy and quality as required by the Food and Drugs Act and Regulations. This is done by filing a drug submission to the TPD.

The following information clarifies the regulation, sale and importation of electronic smoking products:

 A non-refillable, disposable electronic smoking product (e.g., e-cigarette) prefilled with nicotine (or any other drug or natural health product [NHP]) is considered to be a drug (or NHP)/medical device combination product and requires a drug identification number (DIN) or natural health product number (NPN). In this case, its drug delivery system is to be reviewed for safety and efficacy, but a medical device license is not required.

- A refillable electronic smoking product (e.g., e-cigarette) with nicotine or intended to be used with nicotine (or any other drug or NHP) is considered to be a drug (or NHP) delivery system; therefore, a Class II medical device, and its nicotine (or drug or NHP) component requires a DIN (or NPN). (Please note that no medical device license is to be issued until the associated drug or NHP component has received a DIN or NPN.)
- An electronic smoking product (e.g., e-cigarette) associated with a health claim, but not associated with nor intended to be used with nicotine (nor any other drug nor NHP) is considered to be a Class I medical device.
- An electronic smoking product (e.g., e-cigarette) not associated with any health claim and not associated with nor intended to be used with nicotine (nor any other drug nor NHP) is not regulated under the Food and Drugs Act.

No electronic smoking products have been granted market authorization in Canada including those exempt from the Food and Drugs Act.

Source: Health Canada August 2011

- 1. U.S. Food and Drug Administration. (2010). Consumer updates. E-Cigarettes: Questions and answers [online]. Retrieved February 7, 2012, from http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm225210.htm
- U.S. Food and Drug Administration. (2009). Consumer health information. FDA warns of health risks posed by e-cigarettes, July 2009 [online]. Retrieved February 7, 2012, from http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM173430.pdf
- Vardavas, C. I., Anagnostopoulos, N., Kougias, M., Evangelopoulou, V., Connolly, G. N., & Behrakis, P. K. (2011). Acute pulmonary effects of using an e-cigarette: impact on respiratory flow resistance, impedance and exhaled nitric oxide [online]. Chest. Published online before print December 22, 2011. doi: 10.1378/chest.11-2443. Retrieved February 7, 2012, from http://chestjournal.chestpubs.org/content/early/2011/12/21/chest.11-2443.short?rss=1
- 4. Health Canada. (2009). Health Canada advises Canadians not to use electronic cigarettes (Advisory 2009-53, March 27) [online]. Retrieved February 7, 2012, from
 - http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2009/2009_53-eng.php
- U.S. Food and Drug Administration. (2009). Summary of results: Laboratory analysis of electronic cigarettes conducted by FDA [online]. Retrieved February 7, 2012, from http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm
- Smoking and Health Action Foundation/Non-Smokers' Rights Association(2013). Report of the Forum on E-cigarettes.January 30, 2013. Toronto, Ontario.

- 7. U.S. Food and Drug Administration. (2009). Summary of results: Laboratory analysis of electronic cigarettes conducted by FDA [online]. Retrieved February 7, 2012, from http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm
- 8. U.S. Food and Drug Administration. (2009). Summary of results: Laboratory analysis of electronic cigarettes conducted by FDA [online]. Retrieved February 7, 2012, from http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm
- Health Canada. (2009). Health Canada advises Canadians not to use electronic cigarettes (Advisory 2009-53, March 27) [online]. Retrieved February 7, 2012, from http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2009/2009_53-eng.php
- Health Canada. (2009). Health Canada advises Canadians not to use electronic cigarettes (Advisory 2009-53, March 27). Retrieved February 7, 2012, from
- http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2009/2009_53-eng.php
- 11. Etter, J.-F., Bullen, C., Flouris, A. D., Laugesen, M., & Eissenberg, T. (2011). Commentary: Electronic nicotine delivery systems: a research agenda [online]. Tobacco Control, 20, 243–248. Retrieved February 7, 2012, from http://tobaccocontrol.bmj.com/content/early/2011/03/17/tc.2010.042168
- 12. Health Canada. (2009). Health Canada advises Canadians not to use electronic cigarettes (Advisory 2009-53, March 27) [online]. Retrieved February 7, 2012, from http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2009/2009_53-eng.php
- World Health Organization. (2008). Marketers of electronic cigarettes should halt unproved therapy claims [online]. News Release September 19, 2008. Retrieved February 7, 2012, from
- http://www.who.int/mediacentre/news/releases/2008/pr34/en/index.html
- 14. Bupropion is available in Canada as the anti-depressant Wellbutrin® SR and the smoking cessation drug Zyban®. Bupropion helps smokers quit by controlling nicotine withdraw and reducing urges to smoke. (Health Canada. (2009). Nicotine replacements and medications for quitting smoking [online]. Retrieved February 7, 2012, from http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/body-corps/aid-eng.php)
- 15. Varenicline (Champix®) is a nicotine receptor partial agonist that reduces nicotine withdrawal and cravings and that prevents pleasurable effects of smoking. (Alberta Health Services. (2007, revised 2011). Tobacco basics handbook, third edition [online]. Retrieved February 7, 2012, from http://www.albertahealthservices.ca/AddictionsSubstanceAbuse/if-res-tbh-cessation.pdf
- World Health Organization, (2013). Questions and answers on electronic cigarettes or electronic nicotine delivery systems (ENDS). Juky 9, 2013. Retrieved July 15, 2013 from
- http://www.who.int/tobacco/communications/statements/eletronic_cigarettes/en/index.html
 17. Lindsay McCauley,Lindsay;Markin,Catherineand Hosmer, Danielle(2012). An Unexpected Consequence of Electronic Cigarette Use. Chest 2012;141;1110-1113 DOI 10.1378/chest.11-1334. Retrieved July 15, 2013 from http://chestjournal.chestpubs.org/content/141/4/1110.full.html
- Henningfield, J. E., & Zaatari, G. S. (2010). Editorial: Electronic nicotine delivery systems: emerging science foundation for policy [online]. Tobacco Control, 19, 89–90. doi:10.1136/tc.2009.035279. Retrieved February 6, 2012, from http://tobaccocontrol.bmj.com/content/19/2/89.extract
- 19 Szendre, K., Matzen, W., , Osiander-Fuch, H., Heitmann, D., Schettgen T., Jörres, R. &, Fromme, H. (2013). Use of electronic cigarettes (e-cigarettes) impairs indoor air qualityand increases FeNO levels of e-cigarette consumers. International Journal of Hygiene and Environmental Health
- 20 National Institutes of Health. (2006). State-of-the-Science Conference onTobacco Use: Prevention, Cessation and Control. Maryland.
- 21 World Health Organization. (2014). Electronic nicotine delivery systems. Conference of the Parties to the WHO Framework Convention on Tobacco Control. Moscow, Russia
- 22 Ohlheiser, Abby (2014). Big tobacco companies are putting big warning labels on their e-cigarettes. The Washington Post. http://www.washingtonpost.com/news/to-your-

health/wp/2014/09/29/big-tobacco-companies-are-putting-big-warning-labels-on-their-e-cigarettes/