

E-cigarettes – anything but harmless

BfR FAQ of 25 June 2020

The term “e-cigarette” stands for electronic cigarette, which contains a nicotinic fluid – also known as e-liquid – instead of tobacco. During vaping, this liquid is heated and vaporised using a battery-powered heating element. The composition of the liquid, which is contained in a cartridge or a tank, depends on the specific product and therefore varies greatly. Health risks for “vapers” can result from nicotine, other active substances, smoke simulants, additives and possibly impurities. The vapour from e-cigarettes can contain substances which are harmful to health and which can also be inhaled by passive vapers. Very little is currently known about the long-term health effects.

How does an e-cigarette work?

An e-cigarette consists of a vaporiser with a battery-powered heating element, a cartridge or a tank containing the liquid being vaporized and a battery. Refill packs are available for the cartridges. In contrast to conventional cigarettes, tobacco is not burned; instead the liquid is heated and vaporised at 150 to 200 degrees Celsius in most devices. The e-cigarette is a further development of the “nicotine inhaler”, which looks like an inhalation device that is used as a medical device for smoking cessation.

What does the liquid used with e-cigarettes actually contain?

Due to the large number of different products, only a few substances can be named. The main ingredients are usually propylene glycol and/or glycerol. They serve as a smoke simulant and as a solvent for other ingredients. These include nicotine and aromatic (such as ethyl acetate, linalool and tabanon) and flavouring substances (e.g. vanilla extract, menthol or malic acid). In an US study, pharmacological agents (e.g. a drug to treat erectile dysfunction and an appetite suppressant) were detected. The BfR does not know whether such products are available in Germany.

What are e-shishas?

Contrary to what the name shisha suggests, e-shishas are not electrically powered hookahs, but e-cigarettes that usually contain no nicotine. Some of the e-cigarettes offered as e-shishas are based on the taste of hookah smoke. Mouthpieces similar to those used for hookahs are also used in some cases. E-shishas are offered in numerous forms.

What are the different models of e-cigarettes?

The technical aspects of e-cigarettes are subject to continuous development. First generation models resemble a tobacco cigarette and are disposable products. Second generation devices are more powerful and refillable. Third generation e-cigarettes can be modified in terms of their voltage or power. They are known as “mods”. Temperature and airflow can also be adjusted on the latest devices. So-called “sub-ohm” devices develop more vapour, which leads to higher nicotine absorption and a more intense taste experience. The vapour is inhaled directly.

Do e-cigarettes always contain nicotine?

Most e-cigarette liquids contain nicotine. However, nicotine-free liquids are also available. The wide variety of products currently available makes it impossible to issue a general statement about the nicotine content of liquids and the amount that is absorbed when vaping.

Are the ingredients of the liquids declared on the packaging?

Liquids containing nicotine are subject to Tobacco Product Ordinance, according to which all ingredients must be declared. However, this regulation does not apply to liquids without nicotine. In this case, labelling is not required under tobacco law. During testing, it was found that the declaration of allegedly nicotine-free products was often incorrect. In addition, the labelling of the nicotine-containing liquids were often insufficient or incorrect. E-cigarette users therefore often have no reliable information about which substances they inhale.

Are e-cigarettes – with and without nicotine – harmful to health?

According to current knowledge, the vapour of e-cigarettes contains significantly smaller amounts of carcinogenic or other harmful substances compared to the smoke of tobacco cigarettes. This applies to the intended use. However, vaping can be associated with health risks. The aerosols emitted by e-cigarettes - meaning liquid or solid substances suspended in the vapour - can damage the cardiovascular system. Analysis data indicate that carcinogenic substances, such as formaldehyde and acetaldehyde as well as cell-toxic acrolein, may form during vaporisation. The composition of the inhaled vapour varies - depending on inhalation strength, cartridge fill level and battery voltage, as well as the actual design of the device. To date, there have been no long-term studies of how inhalation of the propylene glycol and glycerol smoke simulants affects health. It has been proven that some of the flavourings used in the liquids can cause allergies. Apart from that, nicotine consumption is a health risk factor. It causes increased blood pressure, increased tendency toward thrombosis, release of stress hormones and increased formation of gastric acid. The risk of cardiovascular diseases and stroke. From BfR's point of view, nicotine addiction already constitutes a health impairment. Health concerns also exist with nicotine-free e-cigarettes. Because of the variety of products, it is often unknown which substances are contained in the liquids. Cases of poisoning among e-cigarette users must be evaluated against this backdrop. Another health risk is posed by the accidental swallowing of liquids - especially after self-mixing, which is therefore strongly discouraged. There is a health risk of severe or even lethal poisoning.

How does the smoke simulant propylene glycol often used in e-cigarettes take effect?

Sensitive people may experience eye irritation and shortness of breath. After inhalation, a large part of the propylene glycol initially remains in the lungs. In experiments in which laboratory animals inhaled propylene glycol for prolonged periods, changes in the blood count were detected. Nothing is known about the long-term effects on humans. It is also not known whether an allergy can be triggered by inhaling propylene glycol. According to the current state of science, it is possible that carcinogenic aldehydes are formed when smoke simulants (propylene glycol or glycerin) are heated. From BfR's perspective, further investigations are required.

Are nicotine-free liquids harmless to health?

No. Nicotine-free liquids also consist of smoke simulants, flavouring substances and aromas, which pose health risks as with nicotine-containing liquids. The ingredients of the vapour may damage the cardiovascular system. Vaping can form carcinogenic substances such as formaldehyde and acetaldehyde as well as cell-toxic acrolein. There are also no long-term studies of how inhalation of the smoke simulants propylene glycol and glycerol affects health. In principle, all liquids must meet the requirements of product safety law: A product must therefore not endanger the safety and health of people when used as intended or foreseeable. However, nicotine-free liquids are not subject to the tobacco law that applies to nicotine-containing liquids. As a result, nicotine-free liquids may contain substances that are prohibited in nicotine-containing liquids. These can also include substances that have not been examined and assessed for their health effects when inhaled. The ingredients are often not stated because mandatory declaration is not required.

How are e-cigarettes and e-liquids regulated by law?

In the European Union, the legal provisions depend on whether the products contain nicotine. If this is the case, the EU Tobacco Products Directive (2014/40/EU) applies. In Germany, further legal regulations and provisions can be found in the Tobacco Product Act (Tabakerzeugnisgesetz) and in the Tobacco Product Ordinance (Tabakerzeugnisverordnung). In addition to nicotine, the maximum concentration of which is 20 milligrams per millilitre, other ingredients are regulated separately in German tobacco law. Hazardous substances (e.g. diacetyl or bitter almond oil) as well as substances that have a stimulating effect (e.g. caffeine and taurine) or claim a health benefit (vitamins) are prohibited. Tobacco law also regulates how the products must be designed. For instance, labels must include a warning and information about ingredients and nicotine content. Every e-cigarette product must contain a package insert with instructions for use and storage. These restrictions do not apply to nicotine-free e-liquids as they are not covered by tobacco law. In addition to the tobacco regulations, all e-liquids have to meet the requirements of the Product Safety Act (Produktsicherheitsgesetz) and chemicals law (Chemikalienrecht).

Should you mix liquids for e-cigarettes yourself?

Liquids should not be made by users. Liquids should not contain oils, as inhalation of oils may cause severe respiratory illnesses. The use of E-cigarettes and liquids of unclear origin or composition is also discouraged.

Do e-cigarettes present a passive vaping problem for non-vapers?

E-vapers emit substances in the form of visible vapour into the air in enclosed spaces. According to the current state of science, this may pose health risks to non-vapers. It should also be noted that liquids may contain illegal or unauthorised substances. Neither direct users nor those affected passively can assess whether the vapour poses health risks. In the context of protection for non-smokers, the BfR therefore recommends that e-cigarettes may only be used in smoking areas and that these products are legally treated like conventional cigarettes. E-cigarettes should not be used in the presence of children, pregnant women or sick people.

Can e-cigarettes cause addiction?

It may be assumed that the use of nicotine-containing e-cigarettes can lead to nicotine addiction.

Are e-cigarettes suitable for the cessation of tobacco use?

E-cigarettes represent a way for smokers of conventional tobacco cigarettes, who cannot quit smoking without support, to reduce the intake of toxic substances or to quit. Initial studies show that long-time smokers of tobacco cigarettes can use e-cigarettes as a replacement for tobacco smoking. Apart from that, nicotine inhalers that are licensed for medicinal use and are available in pharmacies are recommended for smoking cessation.

In the United States, vapers died after consuming e-cigarettes. Are the causes of this known?

In the United States, more than 2,800 people suffered severe lung damage after vaping e-cigarettes. According to the American health authority CDC, 68 people died (as of: 18 February 2020). Vitamin E acetate has been linked to these cases. However, it has not been proven that this substance is actually responsible for the diseases. So far, data on the inhalation toxicity of this substance have been few and sometimes contradictory. However, due to its properties, it seems plausible that inhaling high concentrations of vitamin E acetate might

cause lung diseases. The substance presumably accumulates in the alveoli, which would hinder the intake of oxygen. This would also result in inflammation and tissue damage. Many patients in the United States appear to have consumed tetrahydrocannabinol (THC) containing oil. THC is a psychoactive cannabinoid. In the United States, vitamin E acetate is used as a diluent, especially in products that contain drug substances and - according to the US authorities - are offered on the black market. Vitamin E acetate is similar in consistency and colour to THC oils. Therefore, it is suitable for simulating higher concentrations of THC oil in products. Initial analyses by US authorities have shown surprisingly high concentrations of vitamin E acetate in cartridges containing THC. In Germany, nicotine-containing liquids must not contain any vitamins according to the tobacco regulations. When using legally compliant nicotine-containing products, it is therefore unlikely that consumers will purchase e-liquids with a high vitamin E acetate concentration. Nicotine-free e-liquids are not subject to tobacco law, so these restrictions do not apply. In principle, however, both nicotine-containing and nicotine-free e-cigarettes can impair health.

Have there been cases of poisoning with e-cigarettes in Germany?

No fatalities have been reported in Germany related to intended use of or accidents with e-cigarettes. These findings come from an evaluation of enquiries made to German poison centres by the Gesellschaft für Klinische Toxikologie (GfKT) and the BfR within a study linked to establishment of a national poisoning registry (PiMont). In this study, no case of severe poisoning after regular use of e-cigarettes was recorded within the period from mid-2015 to mid-2019. The majority of enquiries to poison centres related to accidental swallowing of the refill solutions (liquids), often by children. These liquids often contained nicotine. Even in small quantities, this substance can cause adverse health effects such as prolonged vomiting. Ingestion of larger amounts of nicotine can be life-threatening.

Independent of the PiMont study, a report in the medical literature indicates that three patients suffering from lung damage required hospitalisation after use of e-cigarettes in Lower Saxony in 2019. Potential other causes for the lung damage were excluded.

Further poisonings related to e-cigarette use were reported in Bremerhaven in 2019: eight adolescents suffered from impairment of memory and consciousness (fainting) as well as from seizures and racing heart. According to a preliminary assessment by the BfR, the symptoms are very probably caused by synthetic cannabinoids contained in the e-liquids. The patients reported they had vaped cannabidiol (CBD). CBD is a weakly psychoactive cannabinoid. CBD e-liquids containing other psychoactive cannabinoids had just been identified in the USA a year prior. The same complaints as those reported by the patients in Bremerhaven were listed in that report.

Are nicotine-containing e-cigarettes and e-liquids controlled in Germany?

The German federal states are responsible for monitoring the safety of all products sold or manufactured in Germany. The authorities check the legal conformity of the products and may take action. Checks can be performed on both a random and ad hoc basis, for example in the event of suspicion.

Can e-cigarette users become infected with the coronavirus if they share the mouthpiece with other users?

Coronaviruses can be transferred to the mouthpiece when an infected person uses an e-cigarette and can survive there for some time. It is therefore possible to infect another person via indirect contact, if the virus reaches the mucous membranes of the mouth. To minimise this risk, e-cigarettes should not be shared with other people. The same applies to conventional cigarettes, pipes and other articles that come into contact with the mouth, such as drinking bottles, glasses, cups, pacifiers.

Can e-cigarettes explode?

Individual reports keep emerging, according to which the batteries installed in e-cigarettes have exploded and caused burn injuries. An evaluation of hospital data from 2018 in the USA showed that around 1,000 such cases were reported annually. Comparable statistical studies are not available for Germany. The BfR recommends only using the chargers and batteries that have been specified by the respective manufacturer.

This text version is a translation of the original German text which is the only legally binding version.