

March 9, 2000

QUESTIONS AND ANSWERS

AIR CLEANERS DESIGNED TO INTENTIONALLY GENERATE OZONE (OZONE GENERATORS)

Q.1 Why has Health Canada issued the warning on ozone generators?

A.1 A risk evaluation by Health Canada on ozone generators in January 1999, concluded that ozone generators pose a risk to the health and safety of the public. The direct and purposeful introduction of ozone into occupied indoor environments is unacceptable and therefore should be avoided. Health Canada is concerned with the adverse health effects that may result from the deliberate exposure of the public to ozone from air cleaners that intentionally generate ozone gas (ozone generators). Ozone is an irritant gas that can cause coughs, chest discomfort, and irritation of the nose, throat, and trachea. Health Canada has received complaints from consumers of respiratory problems when using an ozone generator.

Following a review of current information and in consultation with Health Canada and others, the Canadian Standards Association (CSA) recently made the decision not to certify these products for household use and have issued new interim requirements for commercial units. This warning is aimed at addressing the devices previously certified and sold.

Q.2 Which products are affected?

A.2 A list of ozone generators which Health Canada has been able to identify to date has been prepared. This list includes only those ozone generators which have been certified to Canadian requirements. The brand names may differ from the company name and as such may not be included in this list. One way to identify if a company is selling a product under another brand name is to check the CSA LR number. The LR number is a file number assigned by the CSA to identify a particular company. The LR number will be located on the product usually below or to the right of the CSA certification mark. This list will be updated as new information becomes available to Health Canada.

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Q.3. What if my ozone generator is not on Health Canada's list?

A.3. Health Canada is aware that other brands of ozone generators are being sold in Canada and is investigating the certification status of these products. Consumers are warned that all air cleaners which are designed to intentionally or purposefully generate ozone gas are affected. The presence of at least one ozone-generating plate distinguishes that the ozone production is intentional and is not the unintentional by-product of normal operation of an electrically-operated product. For household use, most products are portable, bread-box sized units that plug into the wall and may have an ozone detector built-in. Some devices may be battery powered and some may be duct-mounted. Most devices have been sold door-to-door and not through retail outlets.

Q.4. How many ozone generators have been sold in Canada?

A.4. It is estimated that about 5,000 units have been sold in Canada over the last two years. This estimate was obtained through data collected by Canada Customs and Revenue Agency. However, one manufacturer has indicated that business volumes in Canada are well over 100,000 units.

Q.5. What is Health Canada's warning to consumers?

A.5. Health Canada is warning consumers not to use an ozone generator in their homes.

Q.6. Does Health Canada's warning apply to the use of an ozone generator in unoccupied spaces?

A.6. Health Canada is concerned about the use of ozone generators in occupied spaces where the public may be exposed to ozone gas. Health Canada's warning does not apply to ozone generators intended for use in unoccupied spaces by trained individuals who are following appropriate occupational health and safety requirements.

Q.7. What is ozone?

A.7. Ozone is a gas. Its molecules consist of three oxygen atoms, designated by the chemical symbol O₃. It is created by lightning in the lower atmosphere and by solar ultraviolet rays in the upper atmosphere. The ozone layer in the upper atmosphere absorbs much of the ultraviolet radiation from the sun, and thus protects life on earth from these harmful rays. However, at ground level, ozone is generated by the action of sunlight on emissions from industry and vehicle exhaust, and is an air pollutant. In an ozone generator, ozone is produced by applying an electrical current to at least

one ozone-generating plate which then charges oxygen in the incoming air and produces ozone.

Q.8 Since I have used an ozone generator in my home, will I be sick?

A.8 The type of adverse health effects one may experience from exposure to ozone will depend on what concentration was received and for how long. For ozone, the dose is linked to the concentration of the gas in the air, the duration of exposure and the rate of air intake (for example, exercising increases the rate of air intake). Some people have reported headaches, sore throats, irritated eyes and laryngitis from using an ozone generator. The symptoms reportedly ceased when the device was turned off. Persons with asthma are more sensitive than the general public to low levels of ozone. Consumers should consult their physician for health concerns related to ozone exposure.

Q.9 What about other types of air cleaners?

A.9 The warning only applies to air cleaners that intentionally generate ozone gas. Health Canada is aware that other air cleaners or other electrically-operated devices may generate ozone as a by-product of their normal operation. Consumers are reminded that other air cleaners such as electrostatic precipitators should be properly installed and maintained according to the manufacturer's specifications.

Q.10 What regulations cover ozone generators?

A.10 Both the *Food and Drugs Act* (FDA) and the *Pest Control Products Act* (PCPA) cover ozone generators. The claimed purpose or representation, as well as where and how the device is used determines which regulations apply. In order to avoid being subject to regulation under the *Food and Drugs Act* and/or the *Pest Control Products Act*, ozone generators continue to be marketed in Canada as "air cleaners" or "pollution control devices" without making medical or biocidal claims or being marked for medical or biocidal purpose or use.

Q.11 How are devices regulated under the *Food and Drugs Act*?

A.11 Prior to July 1, 1998, The *Medical Devices Regulations* of the *Food and Drugs Act* prohibited medical devices which were designed to generate airborne ozone to which humans may be exposed. A limit of 0.05 ppm (vol/vol) was set for other medical devices which generated ozone incidental to their normal operation. However, when the new *Medical Devices Regulations* came into effect on July 1, 1998, the old regulations and schedules ceased to exist and presently there are no

regulations on medical devices that produce ozone. To replace the old Schedule VIII, the Therapeutic Products Programme has drafted a policy on ozone generators. Meanwhile, the new *Medical Devices Regulations* establish general safety and effectiveness requirements for medical devices. The policy describes the performance and quality standards in which to measure the safety and effectiveness of subject devices. Health Canada does not recognize any health benefits from human exposure to ozone and therefore precludes approval of such devices under the *Medical Devices Regulations*.

Q.12 How are devices regulated under the *Pest Control Products Act*?

A.12 The *Pest Control Products Act* requires that manufacturers of devices making biocidal claims (e.g., destroys bacteria, prevents the growth of mould), or that have a biocidal use or purpose, prove that those devices are safe and efficacious before they are marketed in Canada. No applications for registration of air cleaners that intentionally generate ozone have been made to the Pest Management Regulatory Agency (PMRA) to date.

Q.13 Does ozone kill germs?

A.13 To be effective as a germicide, the concentration of ozone must be far greater than any human could tolerate. A study by the U.S. Environmental Protection Agency indicated that ozone was not effective in killing airborne moulds and fungi, even at concentrations as high as 6 to 9 ppm.

Q.14 What regulations exist to cover ozone generators that are not subject to the FDA or PCPA?

A.14 Presently, no regulations for ozone generators exist under the *Hazardous Products Act* (HPA). The jurisdiction for electrical products (such as plug-in type air cleaners) rests with provincial electrical authorities. Each province has adopted an electrical code or regulation which has general rules regarding the sale of electrical equipment. These general rules direct that no person can sell electrical equipment unless it conforms to the applicable standard as certified by an accredited certification organization such as the Canadian Standards Association (CSA).

Q.15 What certification requirements apply to ozone generators?

A.15 Over the last few years, air cleaners that incorporate features that intentionally generate ozone intended for both residential and commercial use have been certified. The previous requirements for such products were contained in Electrical Bulletins Numbers 750B, 750C, 750E and Electrical Certification Notice No. 243C.

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These certification requirements have recently been cancelled and superseded by the requirements contained in Technical Information Letter (TIL) No. H-13.

On November 30, 1998, the Canadian Standards Association (CSA) announced the publication of a TIL No. H-13 which incorporates additional requirements for air cleaners that intentionally generate ozone. Effective November 30, 1998, the CSA does not certify air cleaners that intentionally generate ozone for household use. Manufacturers of devices marked for use in commercial establishments are required to meet additional marking requirements before March 30, 1999 and additional testing requirements before August 1, 1999 as contained in the TIL.

Q.16 What standards apply to ozone generators?

A.16 Ozone generators are subject to common electrical standards, such as those which address fire and shock hazards, as well as the TIL H-13 (effective November 30, 1998), which specifically addresses the intentional exposure to ozone from air cleaners.

Q.17 What should I do with my ozone generator now that Health Canada has warned me not to use it in my home?

A.17 The public should discuss return policies with the manufacturer or distributor from whom he/she purchased the product.

Q.18 Have there been any complaints about ozone generators?

A.18 Health Canada has received complaints from consumers about ozone generators. In two cases, a commercial device was used in the home, and in a separate case residents of a seniors residence complained of respiratory problems allegedly related to an ozone generator (type unknown). After the advisory was issued on February 5, 1999, numerous calls were received from consumers indicating that they had experienced respiratory problems when using an ozone generator in their home.

Q.19 Does the warning also apply to battery-operated air cleaners?

A.19 The warning applies to all air cleaners designed to intentionally generate ozone whether they are plug-in, hard-wired or battery-operated. Health Canada is aware that battery-operated devices will not be captured by the CSA certification requirements.

Q.20. Since Health Canada warns that I should not use my ozone generator in my home, what else can I do?

A.20. There are a number of sanitary practices available to improve indoor air quality and to prevent or solve problems for which ozone generators are currently marketed. The three most common approaches to reducing indoor air pollution, in order of effectiveness, are: source control (eliminate or control the sources of pollution); ventilation (dilute and exhaust pollutants through outdoor air ventilation); and air cleaning (remove pollutants through proven air cleaning methods). The Canada Mortgage and Housing Corporation (CMHC) has published *The Clean Air Guide - How to Identify and Correct Indoor Air Problems in Your Home*. It can be ordered for a nominal fee by calling 1-800-668-2642.