

# AHS PPE Taskforce Guidance

Topic: Technical Grade Ethanol Hand Sanitizer

Date: June 25, 2020

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Health Canada has recently approved the use of technical-grade ethanol in the manufacturing of some hand sanitizer products, in place of pharmaceutical-grade ethanol. With this change, they have released a new risk assessment, as well as new labelling requirements.

We understand and appreciate that staff may be concerned about this new risk assessment and labelling from Health Canada associated with Microsan-brand hand sanitizer products.

Your safety is our priority. We have done a thorough review of the Health Canada assessment and completed additional research, confirming that the use of technical-grade ethanol, now being used in place of pharmaceutical-grade ethanol in the manufacturing of the product, is safe when used as directed.

Staff may notice a stronger or different odor associated with the products manufactured with technical-grade ethanol.

We want to ensure you are proactively informed, and have prepared this FAQ document for your additional information. This outlines Health Canada's new assessment, and related interpretation for human health.

If you would like to consider reducing your use of the hand sanitizer products impacted by this new assessment, we suggest that you replace use of hand sanitizer with warm water and soap, where practical and possible. For more detail, see question 16.

## Question 1: What is ethanol?

Ethanol is a chemical compound. It is the "alcohol" that is consumed in alcoholic beverages. Ethanol has other uses as well, and its disinfectant properties make it a common choice for use in hand sanitizers and other disinfectant products.

## Question 2: What is "USP"- or "pharmaceutical-grade" ethanol?

"USP" stands for United States Pharmacopeia, which is an organization that develops quality and safety standards. USP-grade ethanol, which is also called "pharmaceutical-grade" ethanol, must meet certain purity standards, including maximum limits on the concentration of impurities that may be commonly found in ethanol. For example, the maximum allowable level for acetaldehyde in USP-grade ethanol is 10 micrograms in every liter of ethanol. This is equivalent to a concentration of 10 parts per million (ppm).

### Question 3: What is “technical-grade” ethanol?

Technical grade ethanol has purity standards that are not as strict as USP-grade ethanol. Technical grade ethanol may contain acetaldehyde in the range of 800 to 1000 micrograms in every liter of ethanol. This is equivalent to a concentration of 800 to 1000 parts per million (ppm).

### Question 4: What is a part per million?

A part per million (ppm) is a measure of concentration, or how much of one substance is contained within another substance. For example, if we had a 55-gallon (208 Liter) drum of water and added 4 drops of orange juice to that drum, then the drum would contain 1 part orange juice in a million parts of water; the orange juice concentration would be 1 ppm. If the orange juice concentration was 1000 ppm, then this would be equivalent to pouring just under 1 cup of orange juice into the 55-gallon drum of water.

### Question 5: Why has Health Canada authorized the use of technical-grade ethanol in hand sanitizer?

Due to the COVID-19 pandemic, the demand for hand sanitizer has increased dramatically. This demand has resulted in shortages of key ingredients used in hand sanitizer, such as USP- (or “pharmaceutical-grade”) ethanol. In order to ensure that there is an adequate supply of hand sanitizer, Health Canada has authorized manufacturers to use technical-grade ethanol in the hand sanitizer that they produce.

### Question 6: What is acetaldehyde?

Acetaldehyde is a simple chemical compound made up of carbon, hydrogen, and oxygen, and it is a 2-carbon molecule, similarly to ethanol. It is a colourless liquid at room temperature, with a very strong odour. Acetaldehyde has a high vapour pressure, which means that it evaporates quickly, and much more quickly than ethanol.

### Question 7: How might I be exposed to acetaldehyde?

Acetaldehyde is naturally produced in the environment, and we are all exposed to low levels of acetaldehyde every day in the air we breathe and the food and beverages that we consume. Acetaldehyde is naturally present in a wide variety of foods, including fruits and vegetables, dairy products, seafood, meat, eggs, and nuts, bread products, and alcoholic and non-alcoholic beverages, at concentrations ranging from 0.001 to 400 ppm. Acetaldehyde is also generally recognized as safe for use as a flavouring agent, and it is added to dairy and meat products, fruit juices, baked goods, soft drinks, desserts and candy. It has been estimated that the average adult consumes a total of 35 mg to 200 mg of acetaldehyde every day from food and beverages.

Acetaldehyde is also produced naturally within our bodies as part of normal processes such as amino acid metabolism. Whenever we consume beverages containing ethanol (alcohol), enzymes in our body convert the ethanol into acetaldehyde.

Our bodies are very good at quickly metabolizing the acetaldehyde that enters into or is produced within our bodies, transforming it into chemical products that are used in normal cellular energy production. The eventual end products from acetaldehyde metabolism are carbon dioxide and water.

Because our bodies metabolize acetaldehyde very quickly and effectively, the acetaldehyde that we are exposed to every day does not accumulate in our bodies.

### **Question 8: How might I be exposed to acetaldehyde if I use hand sanitizer that contains technical-grade ethanol?**

Studies of hand sanitizer use have demonstrated that healthcare workers are exposed to small amounts of ethanol whenever they use ethanol-based hand sanitizer. The main route of this exposure is inhalation of ethanol vapour that is given off from the liquid hand sanitizer, as opposed to the ethanol being directly absorbed through the skin.

The vapour pressure of acetaldehyde is much greater than ethanol's vapour pressure, and so acetaldehyde evaporates much more quickly than ethanol. In other words, inhalation of acetaldehyde vapour would be the primary route of exposure to the acetaldehyde contained within the technical-grade ethanol found in hand sanitizer, and very little, if any, would be absorbed through the skin. This is reflected in the Alberta Occupational Health & Safety Code, which specifies an Occupational Exposure Limit for acetaldehyde vapour, and notes that acetaldehyde is not "a substance [that] may be readily absorbed through intact skin".

AHS has performed an occupational exposure assessment, and this demonstrated that when hand sanitizer containing technical-grade ethanol is used, airborne acetaldehyde vapour concentrations are well below the Alberta Occupational Exposure Limit that is intended to protect worker health (see question #13).

### **Question 9: The Health Canada Risk Assessment mentions a concern about potential carcinogenicity – what does "carcinogenicity" mean?**

"Carcinogenicity" refers to the potential for a substance to cause cancer. Labelling a chemical as carcinogenic is a reflection of the hazard that the chemical may pose (i.e. it may cause cancer). However, the label "carcinogenic" does not indicate what the risk of developing cancer is for someone exposed to the chemical (i.e. will it cause cancer?).

### **Question 10: What is the difference between a hazard and a risk?**

A hazard refers to the potential for something to cause harm. Risk refers to the probability that harm will occur if exposed to a hazard. To use a non-chemical example, consider a thunderstorm. A thunderstorm is hazardous because it has the potential to cause harm. Now consider two scenarios, one where you are standing in the middle of an open field while a thunderstorm is directly overhead, and one where you are watching a thunderstorm off in the distance through your living room window while you sit on a sofa. In both of those scenarios, the hazardous nature of the thunderstorm is exactly the same because a thunderstorm always

has the potential to cause harm. However, the risk of being struck by lightning and electrocuted is much greater if you are standing in a field than if you are sitting in your living room.

### **Question 11: Will I get cancer if I use hand sanitizer containing technical-grade ethanol?**

Acetaldehyde has been identified as carcinogenic to experimental animals. As well, acetaldehyde associated with the consumption of alcoholic beverages is considered to be carcinogenic to humans. This indicates that acetaldehyde is a hazard and has the potential to cause cancer. However, this does not automatically mean that you have a risk of getting cancer from using hand sanitizer containing technical-grade ethanol.

Health Canada has indicated that in order for acetaldehyde to potentially cause cancer, it must first cause significant and prolonged tissue damage. Such damage can only occur with chronic exposure to high amounts of acetaldehyde. For example, the experimental animal studies involved rats or hamsters being exposed to high levels of acetaldehyde vapour for 6 to 7 hours per day, 5 days per week, for the lifetime of the animals. High levels of acetaldehyde is very irritating to tissues, and the exposed animals had signs of significant tissue damage and chronic inflammation in their upper respiratory tracts, and many developed cancers in their upper respiratory tracts. The authors of these studies commented that the carcinogenicity of acetaldehyde is mainly due to the process of repeated tissue damage and repair caused by exposure to high levels of acetaldehyde. Exposure to lower levels of acetaldehyde, which do not result in significant levels of tissue damage, is not associated with an increased risk of cancer.

When an alcoholic beverage is consumed, the ingested ethanol is converted to acetaldehyde. Due to enzyme activity of tissues in the oral cavity as well as bacteria in the mouth, acetaldehyde levels in the saliva and oral cavity are much higher than acetaldehyde levels in the blood after ethanol is consumed. As a result, individuals who drink heavily have a high degree of “local exposure” to acetaldehyde in their mouth and throat, which increases their risk of cancers of the upper digestive tract.

Exposure to acetaldehyde through the use of hand sanitizer containing technical-grade ethanol is a very different scenario than the ones described above, with respect to the route of exposure and the amount of acetaldehyde involved. Safe workplace exposure limits (see question #13) for acetaldehyde protect against the possibility of any increased cancer risk. The use of hand sanitizer containing technical-grade ethanol would not result in a greater risk of getting cancer.

### **Question 12: Health Canada has indicated that hand sanitizer containing technical-grade ethanol should have a warning label stating that it is not recommended for use by women who are pregnant or lactating – should I avoid using hand sanitizer if I am pregnant or breastfeeding?**

In studies with experimental animals, injection of high doses of acetaldehyde is associated with fetal death and fetal malformations. The relevance of such observations for the routes (e.g. inhalation, ingestion) and amounts of acetaldehyde that humans are typically exposed to is uncertain.

Acetaldehyde, produced by our bodies after an alcoholic beverage is consumed, may play a role in the development of fetal alcohol syndrome, which is a specific pattern of congenital anomalies found in children of mothers who drank alcohol heavily during pregnancy.

Neither of the above two scenarios are relevant to potential acetaldehyde exposure from the use of hand sanitizer containing technical-grade ethanol. As per question #13, below, any acetaldehyde exposure from the use of hand sanitizer containing technical-grade ethanol in the workplace must be kept below its occupational exposure limit. The occupational exposure limit for acetaldehyde protects against the possibility of effects on pregnancy.

In a study of lactating women who consumed ethanol, both ethanol and acetaldehyde (the latter due to the body's natural metabolism of ingested ethanol) were detected in the blood, and the concentration of ethanol in breast milk was very similar to the blood concentration. However, acetaldehyde was not detected in breast milk, even though considerable amounts of acetaldehyde were measured in the women's blood.

The occupational exposure assessment results demonstrated a considerable margin of safety in respect of occupational exposure when hand sanitizer containing technical-grade ethanol is used. Health Canada has indicated the following warnings regarding hand sanitizer containing technical-grade ethanol: adults only; do not use on broken or damaged skin; do not inhale; not recommended for use by women who are pregnant or breastfeeding. In the event staff would like to consider reducing use of the hand sanitizer products containing technical-grade ethanol, the use of proper hand hygiene with warm water and soap is an alternative.

### **Question 13: Are there limits to how much acetaldehyde I may be exposed to in the workplace?**

The Alberta Occupational Health & Safety Code has specified an Occupational Exposure Limit for airborne acetaldehyde of 25 ppm (45 mg/m<sup>3</sup>). This is a "ceiling" limit, meaning that a worker may not be exposed to acetaldehyde in the air at a concentration exceeding 25 ppm at any time during the work day. This exposure limit is a legal requirement in Alberta.

As acetaldehyde concentration in the air increases, the first symptom that is noticed is irritation of the eyes and respiratory tract (e.g. burning/stinging sensation in the eyes, scratchy throat, irritation of the nose). The limit of 25 ppm was set to prevent eye and respiratory tract irritation, since these symptoms have not been observed to occur at concentrations below 25 ppm.

Animal studies that have identified increased cancer risk or reproductive effects have involved exposure to acetaldehyde in doses much, much larger than 25 ppm. Therefore, by preventing the most sensitive health effects related to acetaldehyde exposure (eye and respiratory tract irritation), the Occupational Exposure Limit also protects against the possibility of increased cancer risk or reproductive effects.

AHS has performed an occupational exposure assessment to determine the degree of exposure to acetaldehyde when using hand sanitizer containing technical-grade ethanol. Several conditions were assessed, from using hand sanitizer at a moderate rate (once every four

minutes) in a normally-ventilated medium-sized room, to using hand sanitizer at a high rate (once every 80 seconds) in a small room with no ventilation. The full report can be found [here](#).

The acetaldehyde levels in the breathing zone of the individual applying hand sanitizer ranged from 0.02 ppm to 0.13 ppm. Therefore, acetaldehyde levels associated with the use of hand sanitizer containing technical-grade ethanol were 192 to 1250 times lower than the Alberta Occupational Exposure Limit of 25 ppm. These results demonstrated a considerable margin of safety in respect of occupational exposure, and should reassure staff that hand sanitizer containing technical-grade ethanol is safe when used as directed. Health Canada has indicated the following warnings regarding hand sanitizer containing technical-grade ethanol: adults only; do not use on broken or damaged skin; do not inhale; not recommended for use by women who are pregnant or breastfeeding. In the event staff would like to consider reducing use of the hand sanitizer products containing technical-grade ethanol, the use of proper hand hygiene with warm water and soap is an alternative.

#### **Question 14: Is the use of hand sanitizer containing technical-grade ethanol safe?**

Hand sanitizer is safe when used as directed, whether it contains USP-grade (or “pharmaceutical-grade”) ethanol, or technical-grade ethanol. Health Canada has indicated the following warnings regarding hand sanitizer containing technical-grade ethanol: adults only; do not use on broken or damaged skin; do not inhale; not recommended for use by women who are pregnant or breastfeeding.

#### **Question 15: When were and where can I anticipate the products with technical-grade ethanol introduced in AHS facilities?**

Microsan products containing technical-grade ethanol were first issued in AHS facilities in the middle of May 2020. Ripgel products containing technical-grade ethanol were first issued in AHS facilities at the end of April 2020.

#### **Question 16: I would like to reduce my exposure to technical-grade ethanol in the newly labeled Microsan-branded hand sanitizer products. What should I do?**

Cleaning of hands is the single most important strategy to protect staff and patients. Hand Sanitizer is safe, convenient and effective; however, soap and water remain a good alternative. Wherever practical and possible, warm soap and water continues to be a recommended hand cleaning approach for all patient care providers, as an alternative to hand sanitizer.

#### **Question 17: The hand sanitizer in my work area is not labelled with the Health Canada warning. How do I know if it contains technical grade ethanol or not?**

AHS has continued to use pharmaceutical grade hand sanitizer in pediatric units, neonatal intensive care units, maternity/child units, labour and delivery units, and at the Alberta Children’s Hospital, the Stollery Children’s Hospital and the Glenrose Rehabilitation Hospital. Health Canada does not require labelling for pharmaceutical grade hand sanitizer, as it does for technical grade hand sanitizer, and so areas with pharmaceutical grade hand sanitizer will not have labels. As our suppliers are able to provide AHS with more pharmaceutical grade hand

sanitizer, the technical grade hand sanitizer will be phased out and labelling will be removed. If you are unsure about the product in your work area and have further questions, please send them to [PPE@ahs.ca](mailto:PPE@ahs.ca).

For questions or concerns please contact [PPE@ahs.ca](mailto:PPE@ahs.ca).