



Frequently Asked Questions about Phthalates for people with CF and families: Phthalates and Pancreatic Enzymes

Below is information about phthalates for people with CF taking pancreatic enzymes.

1. What are phthalates (pronounced “THA-lates”)?

Phthalates are a group of chemicals used in many products, including drugs, medical supplies, toys, vinyl flooring, wall covering, detergents, lubricating oils, food packaging, cosmetics and personal care products, such as nail polish, hair sprays, soaps and shampoos.

2. What do phthalates do?

Phthalates help plastic to be more flexible. In some medications, phthalates help to slow the release of medicine so it works over a long period of time, making the medicine more effective.

3. Why are people concerned about phthalates now?

Public awareness about phthalates in plastics, toys, foods and personal care products is rising. There is concern that these chemicals might be harmful to people’s health. In August 2008, the U.S. passed a law banning some phthalates in children’s toys and childcare products; such laws are already in place in the European Union (E.U.)

4. Why is this important to someone with CF?

Some medications on the market, including some pancreatic enzymes, contain phthalates. Pancreatic enzymes help people with CF digest their food. The enzymes come in capsule form. Inside each capsule are many small “beads” that contain digestive enzymes. Each bead is covered with a special “enteric-coating.” This coating protects the enzymes as they pass through the high acid environment of the stomach and allows the beads to dissolve in the small intestine, where they help digest food. The “enteric-coating” on some beads contain phthalates.

5. How do I find out if my or my child’s enzymes have phthalates?

Ask your CF Clinic about which pancreatic enzymes have phthalates. The phthalates found in some enzymes may include: dibutyl phthalate (DBP), hydroxypropyl methylcellulose phthalate, cellulose acetate phthalate and diethyl phthalate (DEP). One phthalate that has been studied the most, DEHP, is not used in pancreatic enzymes.

6. How might phthalates affect me, or my child?

It is not clear what effect, if any, phthalates have on humans. Little is known about how they may affect a person’s health. Studies of animals exposed to extremely high levels of certain phthalates have shown potential toxicity to the liver, kidney and reproductive tract. Although the coating of several pancreatic enzymes has contained phthalates for decades, there have been no reported toxicity to people with CF.

Because the risk of malnutrition from not taking pancreatic enzymes is much greater than the potential risk related to phthalates, the Canadian Cystic Fibrosis Foundation's (CCFF) Clinic Subcommittee advises that people with CF to continue taking pancreatic enzymes as prescribed.

7. Should I or my child stop taking enzymes, which have been medically prescribed and which may contain phthalates?

The CCFF's Clinic Subcommittee recommends that **people with CF continue taking their pancreatic enzymes**. It is important for you to talk to your CF Clinic before you or your child changes, or stops taking any CF medications.

People with CF who stop taking pancreatic enzymes are at risk of malnutrition. When people with CF do not take enzymes, they may have poor weight gain or weight loss; foul-smelling, frequent, loose and/or large bowel movements; mucus or oil in the bowel movement; gas and/or stomach pain; and distention or bloating; and may be at risk for distal intestinal obstruction syndrome.

8. Are there pancreatic enzymes that do not have phthalates?

Yes, some pancreatic enzymes have fewer or no phthalates. It is important to talk with your CF doctor about the enzymes you are taking. Remember, for people with CF, the risks of not taking pancreatic enzymes are greater than the potential risk from phthalates.

9. Should I or my child switch enzymes?

People with CF should **continue** to take their pancreatic enzymes as prescribed by their CF doctor. Your current regimen of therapies has been maximized for your health. These enzymes have been used in CF patients for decades with no known problems resulting from phthalates. Switching enzymes could have a negative impact on your or your child's health.

10. How can I reduce my or my child's everyday contact to phthalates?

It is difficult to know what products contain phthalates. Manufacturers are not required to list the phthalate contents of products. However, due to public concerns about this issue, and new laws, information about the phthalate content of products is becoming more available. Some companies have started to decrease the use of phthalates. More products say "phthalate-free" on the label. However, it is important to remember that the safety of other chemicals used is unknown.

In August 2008, the U.S. passed a law to ban phthalates in children's toys and childcare products, which is similar to a law in the European Union (E.U.). In addition, Wal-Mart and Toys"R"Us announced plans to stop selling children's toys containing some phthalates by January 1, 2009.

11. Can phthalates be removed from the body?

Your body will naturally remove phthalates through your urine. Phthalates do not appear to build up in the body.

12. How did the CCFF find out about phthalates in pancreatic enzymes?

The CCFF learned about this issue in 2008 when Canadian researchers unexpectedly found more phthalates in the urine of children with CF taking pancreatic enzymes.

13. What is the CCFF doing about this issue?

The CCFF is collaborating in establishing a working group of CF experts from Canada, the United States, and Europe to evaluate phthalates and learn more about any potential risk to people with CF. The CCFF will continue to keep the CF community informed about matters concerning phthalates and pancreatic enzymes, in a timely way.

14. What is Health Canada, or the Food and Drug Administration (FDA), doing about this?

The CCFF is working closely with the Health Canada, the FDA and the U.S. CF Foundation on this issue. In an August 2008 joint telephone conference, the FDA reinforced that people with CF should continue taking their pancreatic enzymes because the benefits of good nutrition outweigh any potential risk from phthalates.

While the following comment is not directly related to pancreatic enzymes, Health Canada offers this information on the HC Phthalate Information Web site:

The Government of Canada has worked with the plastics industry to have some phthalates removed from the manufacture of children's soft vinyl products in Canada, and phthalates are no longer found in soft vinyl teething and baby products. The Medical Devices Bureau of Health Canada is developing Clinical Practice Guidelines to assist in the proper administration of devices plasticized with phthalates during health care delivery. There is active research and assessment continuing on phthalates.

15. Where can I learn more about phthalates?

Here is a list of resources:

- Phthalates – Canadian Cancer Society
http://www.cancer.ca/ccs/internet/standard/0,3182,3172_1706523966_langId-en,00.html#anchor5.
- Medications as a Source of Human Exposure to Phthalates – case report May 2004 from Environmental Health Perspectives –
<http://www.ehponline.org/members/2004/6804/6804.html>.
- Spotlight on Phthalates from the CDC's Third National Report on Human Exposure to Environmental Chemicals -
http://www.cdc.gov/exposurereport/pdf/factsheet_phthalates.pdf