

Frequently Asked Questions about Phthalates and Pancreatic Enzyme Products



CF Trust version for people with CF and their families

The Cystic Fibrosis Trust wants to inform you of a recent unexpected finding related to pancreatic enzymes. Researchers found levels of phthalates (pronounced “THA-lates”) in the urine of children with Cystic Fibrosis who were taking pancreatic enzymes. Further investigation revealed that some of the enzymes people with CF take to digest food and absorb nutrients contain phthalates.

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

1. What are phthalates?

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. In certain animal studies, very high concentrations appear that they may be harmful, but this has not been shown to be the case in studies in people.

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 allows the beads to dissolve in the small intestine. The digestive enzymes are then released in the small intestine to help digest food. It is the ‘enteric-coating’ on the beads that may contain phthalates.

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

Talk with your CF Centre about which pancreatic enzymes have phthalates. These ingredients also should be in the information you receive from the pharmacy about your enzymes. The phthalates that are found in some enzymes may be listed as: 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 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. Because **the risk of malnutrition from not taking pancreatic enzymes is much greater than the potential risk related to phthalates, we advise that people with CF continue taking their pancreatic enzymes as prescribed.**

7. Should I or my child stop taking enzymes?

The CF Trust recommends that people with CF continue taking their pancreatic enzymes. It is important for you to talk to your CF Centre before you or your child stops taking or changes any CF medications.

8. What will happen if I or my child stops taking the pancreatic enzymes that have phthalates?

People with CF who stop taking their pancreatic enzymes are at risk of malnutrition. When people with CF do not take enzymes, they may have poor weight gain; 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.

9. 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 as not all enzymes work effectively in all people. Remember, for people with CF, **the risks of not taking pancreatic enzymes are greater than any potential risk from phthalates.**

10. 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 problems resulting from phthalates. Switching enzymes could have a negative impact on your or your child's health.

11. 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 on this issue and new laws, 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.

12. Can phthalates be removed from me or my child's body?

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

13. Do Phthalates cause urinary symptoms?

Phthalates are excreted in urine but there is nothing at present to suggest an association with cystitis, or urine infection.

14. How did the CF Trust find out about phthalates in pancreatic enzymes?

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

15. What is the CF scientific community doing about this issue?

The CF Trust, along with the European CF Society is working with CF experts in the US, Canada and Europe to evaluate phthalates and learn more about any potential risk to people with CF. We will continue to keep the CF community informed of what we learn.

In an August 2008 joint telephone conference with the CF Foundation, the Canadian CF Foundation and Health Canada, it was reinforced that people with CF should continue taking their pancreatic enzymes because the benefits of good nutrition outweigh any potential risk from phthalates.

16. 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>

<http://www.phthalates.com/RAs>

<http://ec.europa.eu/enterprise/chemicals/legislation/markrestr/>.

The European Union Directive 76/769/EEC bans some phthalates in children's toys and childcare products

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1976L0769:20071003:EN:PDF>