

1. The "no evidence" formulation on the human health risk is a problem. Dupont has formulated a statement for this issue in the US^{3M1}.

Dupont no longer uses a "no evidence" claim. Instead, they say than no human health effects are "known to be caused" by PFOA. Thus they focus on the lack of consensus on whether PFOA "causes" human health effects.

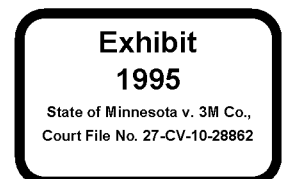
2. OSPAR has found PFOS to be a PBT. Did they reach a completely different conclusion on PFOA, or have they deferred action on PFOA awaiting further data. A direct quote from an OSPAR document would be preferable.

3. The voluntary commitment about the 50% reduction was an LOI commitment; it was not part of an EPA agreement.

4. On the EPA statement about products, it is best to say that EPA stands behind its past statement (now over 2 years old.) Please do not a statement about how EPA has "reviewed the evidence" since that may not be true depending on the context of the statement.

5. The "high-heat processing" reference to PFOA in consumer products would seem important for a European statement in light of the EU's recent determination on PFOA in cookware. I think that they were clear that sintering was key aspect of their comfort with cookware coatings.

6. The discussion of PFOA's toxicity profile in this document could be misleading. We would recommend that, on the cancer issue, acknowledge the animal tumor data, including the mammary tumors, say that the relevance of these data to humans is in question and note that EPA and other governments are working to resolve this question. On the other toxicology issues, focus the question and then give a precise answer or just stay with the Dupont "known to be caused" formulation of the more general safety issue^{3M2}.



3M_MN01525833

Plastics Europe - Q&A ON PFOA

25 Jan 2005

Key messages

- PFOA is a man-made surfactant (detergent-like material) used as an essential processing aid in the manufacture of some fluoropolymers.
- PFOA has been detected at very low concentrations in the environment, and in the blood of the general population of the US and some other countries.
- PFOA is not generally found in articles fabricated from fluoropolymers and sold to the public. For example PFOA cannot normally be detected in non-stick coated cookware. The US Environmental Protection Agency (US EPA) has reviewed the evidence and concluded that “*EPA does not believe there is any reason for consumers to stop using any consumer or industrial related products*”.

Suggested 3M edit:

Because PFOA is a manufacturing aid to make fluoropolymers, it is not generally found in finished products. For example, PFOA is used to make fluoropolymers used in non-stick coatings for cookware. Thus, the presence of PFOA cannot normally be detected in the non-stick coated cookware. The US Environmental Protection Agency (US EPA) has reviewed the evidence and concluded that “EPA does not believe there is any reason for consumers to stop using any consumer or industrial related products”.

- There is no evidence of adverse health effects in the general population resulting from PFOA exposure.
- Medical monitoring of PFOA production employees over 25 years, has shown no evidence of adverse health effects attributable to PFOA among exposed employees. This conclusion is supported by numerous clinical and epidemiologic studies. Exposed employees may have much higher blood concentrations (up to 1000 times higher than the general public).
- Fluoropolymer producers have made a voluntary commitment to the US EPA to reduce worldwide the emissions of PFOA by at least 50% by 2006 (based on year 2000 emissions).
- There are no known substitutes for PFOA in the manufacture of fluoropolymers after more than 30 years of research.

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Q1: What is PFOA?

PFOA (usually the ammonium salt of PerFluoroOctanoic Acid) is a man made surfactant or detergent-like substance used as an essential processing aid in the manufacture of some fluoropolymers, such as PTFE or PVDF. Fluoropolymers are industrial materials used primarily in the automotive, electronics, chemical processing and aerospace industries, as well as in some consumer applications such as cookware.

PFOA may also be referred to as APFO or C8.

Q2: Why has PFOA been brought to the attention of regulators & reported in the press?

PFOA has been detected at very low concentrations in the blood of the general population of the USA and some other countries and in the environment. Therefore, several regulatory bodies have decided to seek additional information about PFOA. The fluoropolymer industry fully shares their commitment to safeguard human health and the environment, and has cooperated with regulators to provide the information requested.

Q3: Is PFOA found in the environment, how did it get there and what happens to it?

PFOA is found in the environment at very low levels. The origin and the mechanisms by which it entered the environment are not well understood and are the subjects of ongoing studies

PFOA does not degrade easily in the environment but the priority review performed by the international OSPAR Convention for marine protection showed that PFOA does not meet the criteria for bioaccumulation and toxicity. OSPAR therefore does not expect an impact on the marine environment.

Q4: Is PFOA found in people's blood and does it do them any harm?

PFOA has been found at very low concentrations (on average about 5 parts per billion) in the blood of the general population of the US and some other countries.

There is no evidence of adverse health effects in the general population resulting from PFOA exposure. ~~No causally related effects have been consistently reported on the health of occupationally exposed workers having much higher blood concentrations (up to 1000 times higher than the general public).~~ 3M comment:

This is supported by research involving thousands of production employees that generally have higher levels of exposure to PFOA than the general public.

Q5: What is the toxicity of PFOA when tested in animals?

~~PFOA administered to rodents exposed for long periods resulted in blood concentrations much higher than found in PFOA workers and showed weight loss, toxicity to the liver and benign tumours of the liver, the testes and the pancreas.~~

~~Biochemical and further toxicity studies have shown that the mechanisms causing benign liver and testicular tumours are not likely to be relevant to humans. The mechanism responsible for the benign pancreatic tumours remains the subject of active investigation.~~ 3M edit:

PFOA administered to laboratory animals exposed for long periods have resulted in blood concentrations much higher than found in PFOA workers and showed weight loss, toxicity to the liver and benign tumours of the liver, the testes and the pancreas. Biochemical and further toxicity studies have shown that the mechanisms causing benign liver and testicular tumours are not likely to be relevant to humans. The objective of animal laboratory studies is to find out the biological effects of a chemical and how much does it take to produce that effect. Not all effects in laboratory animals occur in humans and other species because of biological differences.

Q6: Is PFOA present in articles sold to the public and is my cookware safe?

The processing conditions used in the manufacture of fluoropolymer consumer articles are known to drive off or destroy PFOA.

Migration studies have not detected PFOA in non-stick (PTFE-coated) cookware under normal manufacture and use conditions.

Traces of PFOA have been detected under aggressive extraction conditions from finely divided coating material removed from the surface of the cookware. There were conditions that do not occur during normal use of the cookware.

The US Environmental Protection Agency (US EPA) has stated that "*EPA does not believe there is any reason for consumers to stop using any consumer or industrial related products*".

Q7: What are the regulatory authorities doing in the USA and elsewhere?

There is no specific regulation for the manufacture and use of PFOA in the US or in Europe. A draft Risk Assessment has been published by the US-EPA in January 2005. It is now under review by an independent Science Advisory Board.

Outside the USA several national governments, the European Union and the OECD are gathering data on perfluorinated chemicals including PFOA. Germany is performing environmental and health risk assessments on PFOA.

Q8: How did the fluoropolymer producers react to the finding of the presence of PFO in the environment?

Fluoropolymer producers made a voluntary commitment to the US EPA to reduce worldwide the emissions of PFOA by at least 50% by 2006 (based on year 2000 emissions).

Q9: What is the toxicological profile of PFOA?

The scientific evidence shows that PFOA is not B (bioaccumulative) or T (toxic) using the prevalent PBT criteria. It is not genotoxic, nor a human carcinogen, nor a reproductive toxin. PFOA has no effect on reproductive and thyroid hormones in workers, or reproductive effects in laboratory studies. Based on our analysis of all available data, we do not consider PFOA to be a developmental toxin.

Q10: What is the relation between PFOA and PFOS?

~~The widespread distribution of PFOA was noted during a study on PFOS, another perfluorinated chemical. PFOS had a number of dispersive uses, was produced in far greater quantities than PFOA. PFOS has a number of recognised toxic effects and is bioaccumulative.~~

3M edit:

PFOS and PFOA are both part of the perfluorooctanyl chemistry. Historical uses of PFOS and PFOS-related products include fire fighting foams and stain resistant materials. PFOA is an essential aid to make fluoropolymers and is often consumed during this manufacturing process. Uses of PFOA include critical applications such as products for military and civilian aircraft. Both compounds are found to be widespread in the environment at low levels. Investigations into the sources of PFOS and PFOA in the environment are continuing. Research of the levels of exposure of production employees has shown no adverse health effects from either PFOS or PFOA.