

**06-096 C.M.R. Chapter 890: Designation of PFOS as a Priority Chemical
Basis Statement and Response to Comments**

Basis Statement: The final rule designates perfluorooctane sulfonic acid (“PFOS”) and specific salts of PFOS as priority chemicals and requires reporting for certain categories of product that contain these regulated chemicals and that when used or disposed of will likely result in a child under 12 years of age or a fetus being exposed to these chemicals. The final rule applies to manufacturers of specified product categories that contain intentionally added amounts of these chemicals and seeks to gather information which would clarify the prevalence of use of the listed chemicals.

The designation of PFOS and its salts as Priority Chemicals meets the statutory criteria for designation as specified in 38 M.R.S. §1694(1). Maine CDC concurrence for the proposed rule is based on the chemicals’ category 1A reproductive toxicity classification on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). The Department hereby accepts and adopts by reference the Maine CDC PFOS Priority Designation Concurrence Letter, dated February 23, 2018, which is attached and incorporated into this Basis Statement. The Department also accepts and adopts by reference the underlying science, data, and documents that Maine CDC developed and utilized with respect to its February 23, 2018 letter.

As this Chapter applies to manufacturers or distributors of certain products, the fiscal impacts will fall mainly on manufacturers of consumer products which contain intentionally added amounts of the proposed priority chemicals. Filing the required report information with the Department is expected to impose only nominal costs. Regulated entities are also expected to pay a one-time reporting fee to the Department to cover the costs associated with information management. This fee is dependent upon the number of regulated products and the concentration of the priority chemical in each.

The proposed rule was originally posted for Departmental rulemaking with a public comment period beginning April 3, 2019. A Department public hearing was held on April 23, 2019, and the comment period closed May 6, 2019. After the close of this initial public comment period, new information about the prevalence of PFOS in Maine’s biosolids highlighted the continuing possibilities of exposure and caused the Department to undertake revisions to the draft rule. This initial rulemaking period terminated with no formal action by the Commissioner. Effective September 19, 2019, responsibility for all rulemaking shifted to the Board of Environmental Protection. A new rulemaking proceeding was initiated by the Board’s posting of the Department’s revised draft rule for a thirty-day written public comment period beginning on October 2, 2019 and closing on November 4, 2019. Before the close of the comment period six requests for a public hearing were received. The comment period was reopened on January 1 and the Board held a public hearing on January 23, 2020. The Department made changes to the draft rule to include specific salts of PFOS and other minor changes, and the Board reopened the comment period on February 3, 2020. This final comment period closed on March 9, 2020. Comments submitted during each of these comment periods are detailed below.

RESPONSE TO COMMENTS

This document summarizes and responds to all substantive comments offered on the proposed rulemaking by members of the public at the public hearings and in writing during the public comment periods as described above.

Comments were received from the following:

Commenter 1: Michael Kuhns, Twin Rivers Paper Company

Commenter 2: Patrick MacRoy, Environmental Health Strategy Center; Phelps Turner, Conservation Law Foundation; Alice D. Elliot, Sierra Club Maine; and Dana Colihan, Toxics Action Center

Commenter 3: Oyeode Taiwo, 3M Company

Commenter 4: Grace Cain, Kennebunk

Summary of Comments and Department Response

1. Comment: Commenter supports the rule as drafted. (Commenter 1)

Response: No changes were made in response to this comment.

2. Comment: Commenter believes that the rule should include those substances that form PFOS through decomposition, degradation, or metabolism (referring to those substances as “precursors”) based on the commenter’s interpretation of the statutory definition of “chemical”. Commenter states that the inclusion of PFOS precursors is vital to addressing the threats posed by PFOS itself. According to the commenter, the inclusion of PFOS precursors would recognize that the exposure potential for PFOS may be largely driven by the presence of its precursors, particularly now that the majority of PFOS production in the U.S. has been phased-out. (Commenter 2)

Response: As required by 38 M.R.S. Chapter 16-D §1694, both the Department and the Maine Center for Disease Control and Prevention reviewed the statutory requirements for Priority Chemical designation relative to PFOS and its salts. One of these requirements is that a chemical must appear on Maine’s Chemicals of High Concern list (38 M.R.S. Chapter 16-D §1693-A) to be considered for priority designation. “PFOS and its salts” appear on this list. Whereas precursors themselves have unique chemical identities, they would need to go through the same scrutiny of having been listed as Chemicals of High Concern before being eligible for Priority status. Because those chemicals commonly identified as precursors of PFOS have not gone through such a review and do not appear on Maine’s Chemicals of High Concern list, it is the Department’s interpretation that the current law does not provide the authority to circumvent this requirement in the manner suggested by the comment. No changes were made in response to these comments.

3. Comment: Commenter seeks an expansion of the definition of “Children’s Products” from the original draft rule as posted on April 3, 2019 (which included certain product definitions that were specific to children under 12 years of age) in order to include a broader range of consumer products that manufacturers will be required to report. Commenter seeks this change in order to include consumer

products that will likely result in a fetus being exposed to the Priority Chemical. Commenter also sought further clarifications of these definitions as contained in the draft posted on October 2, 2019. (Commenter 2)

Response: The Department amended the April 3, 2019 draft rule to expand the range of consumer products captured by the rule as the commenter suggests. To accomplish this, the specificity of age associated with certain children's product definitions in the draft rule has been removed. The revised draft sought to clarify applicability of the rule such as eliminating age associated with product use and product category specificity, while maintaining consistency with the level of detail in current program rules. These changes were included in the revised draft posted on October 2, 2019. From its experience administering current program rules the Department finds that the proposed language provides a sufficient level of detail for compliance interpretation by the Department and regulated community.

4. Comment: Commenter believes that, because of the significance of the PFOS production phase-out within the U.S., the use of PFOS has decreased to a level that renders the designation of PFOS and its salts as unnecessary, particularly in light of consistently decreasing PFOS serum levels measured in the U.S. population. Commenter suggests that this Priority designation is also duplicative of federal action as the EPA's 2019 PFAS Action Plan intends to evaluate PFAS uses and consider establishing federal maximum contaminant levels in drinking water, having already issued guidance on soil and groundwater remediation for PFOS. Commenter also cites the recently passed National Defense Authorization Act, which includes increased levels of research, reporting, and monitoring related to PFAS as evidence that Maine's Priority designation of PFOS and its salts would be duplicative of federal efforts. Commenter expresses concern that literature analysis associated with this proposed Priority designation was not thorough and did not include the most current peer-reviewed studies which, in some cases, provide conflicting evidence to Maine CDC's rationale for the draft rule. Citing more recent analysis refuting a causal link between PFAS and certain adverse health effects, and the small sample size of studies utilized in the Maine CDC review for Priority designation of PFOS and its salts, commenter suggests that the legal standard for strong credible scientific evidence has not been met in this case. Commenter suggests that the designation of PFOS and its salts is further flawed by several questionable links between PFOS and human health effects, which, therefore, does not meet the Chemical of High Concern hazard criteria as detailed in Maine law. (Commenter 3)

Response: Commenter's assessment of currently available literature on PFAS is a useful summary of information, however, the proposed rulemaking is relative to PFOS and its salts specifically which means that the information provided about the broader PFAS class of chemicals is less relevant to this rule. The Department is confident in the analysis provided by Maine CDC, which provides evidence that PFOS and its salts do meet the statutory criteria for priority designation. Commenter's concern about duplicative policy is focused on federal planning for the capture of largescale information related to the broader PFAS class of chemicals. This proposed rule seeks to determine where PFOS and its salts may be used in common products available in Maine, specifically focused on potential exposure sources in our local communities, information made more reliable and distinct because it is reported directly from the manufacturing source rather than a distilled extrapolation from generalized federal data. The Department, in concurrence with Maine CDC, believes that information gathered through the consumer product

reporting requirement established by this draft rule will provide valuable information about where PFOS and its salts are still used in commerce, which will offer important insight into remaining exposure sources in the general population. No changes were made in response to these comments.

5. Comment: Commenter supports the reporting rule and believes product labelling is more ideal for consumer awareness. (Commenter 4)

Response: No changes were made in response to this comment.



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February 23, 2018

Commissioner Paul Mercer
 Maine Department of Environmental Protection
 17 State House Station
 Augusta, ME 04333

Dear Commissioner Mercer,

The Maine Department of Environmental Protection (DEP) in a November 7, 2017 letter requested concurrence on the designation of perfluorooctane sulfonic acid (PFOS) and its salts as a priority chemical from the Department of Health and Human Services, Maine Center for Disease Control and Prevention (Maine CDC). Maine's Toxic Chemicals in Children's Products law, 38 MRSA §1694 requires the designation of a priority chemical be made in concurrence with the Maine CDC. This letter and accompanying support document provide the DEP concurrence on the designation of PFOS and its salts as a priority chemical.

Priority chemical designation under 38 MRSA §1694 requires that the chemical is listed as a chemical of high concern. Per statute, designation of a chemical of high concern requires strong credible scientific evidence that 1) the chemical is a reproductive or developmental toxicant, endocrine disruptor or human carcinogen; and, 2) the chemical is found to be present in human tissues, the home environment or in a consumer product present in the home. "Credible scientific evidence" is defined by statute¹; however, "strong credible scientific evidence" is undefined by statute or rule. Maine CDC has previously interpreted strong credible scientific evidence as a top-tiered weight-of-evidence determination by an authoritative federal or international government agency, or the presence of multiple scientific studies published in peer-reviewed scientific literature with consistent findings.

In the initial chemical of high concern listing in 2012 and again in a 2015 review, PFOS and its salts met reproductive or developmental toxicant and endocrine disruptor toxicity criteria due to the presence of multiple scientific studies published in peer-reviewed scientific literature with consistent findings of reproductive and developmental toxicity and endocrine disruption². Exposure criteria for presence in human tissues and the home environment were also met with strong credible scientific evidence from national biomonitoring studies and multiple scientific studies published in peer-reviewed scientific literature².

¹ 38 MRSA §1691 8-A defines "Credible scientific evidence" as the results of a study, the experimental design and conduct of which have undergone independent scientific peer review, that are published in a peer-reviewed journal or publication of an authoritative federal or international governmental agency, including but not limited to the United States Department of Health and Human Services, National Toxicology Program, Food and Drug Administration and Centers for Disease Control and Prevention; the United States Environmental Protection Agency; the World Health Organization; and the European Union, European Chemicals Agency.

² Deriving Chemicals of High Concern Process Documentation 2012: [Maine CHC Process Documentation 2012](#)
 Chemicals of High Concern Triennial Update Appendix I 2015: [Maine Triennial Update CHC Inclusion Criteria](#)

At the time of the last chemical of high concern listing review in 2015, no authoritative federal or international government agency listed PFOS, nor its salts, with a top-tier weight-of-evidence determination for reproductive or developmental toxicity, endocrine disruption or human carcinogen. In 2017, the Japanese government updated the classification of PFOS in their Globally Harmonized System of Classification and Labelling of Chemicals (GHS) database from category 1B to a top-tier category 1A classification for reproductive toxicity. The Japanese GHS database is one of several federal and international databases used to identify chemicals of high concern based on reproductive or developmental toxicity, endocrine disruption or human carcinogenesis classification. In addition to the multiple peer-reviewed scientific studies previously identified by Maine CDC toxicologists, there is now an international authoritative governmental agency that lists PFOS with a top-tiered weight-of-evidence determination for reproductive toxicity.

Accordingly, Maine CDC concurs with the designation of PFOS and its salts as a priority chemical. The attached document provides more detail on the evidence supporting concurrence for listing PFOS and its salts as a priority chemical.

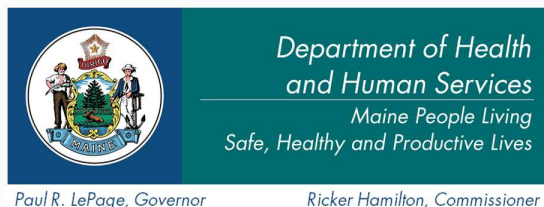
Sincerely,

A handwritten signature in dark ink, appearing to read "Bruce Bates", with a stylized flourish at the end.

Bruce Bates, DO
Director
Maine Center for Disease Control and Prevention

cc: Andrew Smith, SM, ScD, State Toxicologist, Maine CDC

Attachments: Rationale for Concurrence by Maine Center for Disease Control and Prevention on the Designation of Perfluorooctane Sulfonic Acid (PFOS) and its Salts as a Priority Chemical



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Rationale for Concurrence by Maine Center for Disease Control and Prevention on the Designation of Perfluorooctane Sulfonic Acid (PFOS) and its Salts as a Priority Chemical

February 23, 2018

Summary

38 MRSA §1694 requires that the designation of a “priority chemical” under Maine’s Toxic Chemicals in Children’s Products law be made in concurrence with the Department of Health and Human Services, Maine Center for Disease Control and Prevention (Maine CDC). Once a chemical is designated as a priority chemical, the Maine Department of Environmental Protection (DEP) has the authority to establish reporting requirements on the use of the chemical in children’s products, request an alternative chemical assessment, and propose a prohibition on the manufacture, sale or distribution in the State of a children's product containing a priority chemical. In a November 7, 2017 letter, the DEP requested Maine CDC’s concurrence on the designation of perfluorooctane sulfonic acid (PFOS) and its salts as a priority chemical. Maine CDC is informing the DEP of its concurrence with the proposed designation of perfluorooctane sulfonic acid (PFOS) and its salts as a priority chemical.

Under 38 MRSA §1694, designation of a priority chemical first requires the chemical be identified as a chemical of high concern. To be identified as a chemical of high concern, there must be strong credible scientific evidence that 1) the chemical is a reproductive or developmental toxicant, endocrine disruptor or human carcinogen; and, 2) the chemical is found to be present in human tissues, the home environment or in a consumer product present in the home. Maine CDC has previously interpreted strong credible scientific evidence to mean a top-tiered weight-of-evidence determination by an authoritative federal or international government agency, or the presence of multiple studies published in peer-reviewed scientific literature with consistent findings.

When the chemical of high concern list was developed in 2012 and reviewed in 2015, PFOS did not have a relevant top-tiered weight-of-evidence determination by authoritative federal or international agencies. Thus, at the time the existence of strong credible scientific evidence was based on a review of studies published in the peer-reviewed scientific literature. Since 2015, the Japanese government updated its reproductive toxicity classification for PFOS to a top-tier, category 1A listing in its chemical

classification database. Based on the 2017 Japanese authoritative governmental agency listing and the previous review of peer-reviewed scientific literature, PFOS and its salts continue to meet the chemical of high concern toxicity criteria.

Maine CDC in 2012, 2015 and now in 2018 confirmed the presence of multiple biomonitoring studies, including nationally representative studies conducted by the U.S. CDC and studies in peer-reviewed scientific journals, with findings of PFOS in human blood and breastmilk. While national biomonitoring data suggest a decreasing trend in PFOS serum levels, it continues to be detected in adults and children in the U.S. Additionally, multiple studies in the peer-reviewed scientific literature were identified that found PFOS through sampling and analysis to be present in household indoor dust. These findings continue to provide strong credible scientific evidence that PFOS is present in the human body and household environment.

Collectively, PFOS and its salts continue to meet the chemical of high concern listing criteria with strong credible scientific evidence and may appropriately be listed as a priority chemical.

Background

Under 38 MRSA §1694, a chemical must first be identified as a chemical of high concern in order to be designated a priority chemical. The statutory criteria for being designated a priority chemical is identical to that for being designated a chemical of high concern (38 MRSA §1693-A and §1694). To be designated a chemical of high concern, there must be strong credible scientific evidence that 1) the chemical is a reproductive or developmental toxicant, endocrine disruptor or human carcinogen; and, 2) the chemical is found to be present in human tissues, the home environment or in a consumer product present in the home. Credible scientific evidence is defined by statute as results of a study, the experimental design and conduct of which have undergone independent scientific peer review, that are published in a peer-reviewed journal or publication of an authoritative federal or international governmental agency (38 MRSA §16918-A). Strong credible scientific evidence is undefined by statute or rule. Maine CDC has interpreted strong credible scientific evidence to mean a top-tiered weight-of-evidence determination by an authoritative federal or international government agency, otherwise, the presence of multiple scientific studies published in peer-reviewed scientific literature with consistent findings. As there are no authoritative governmental databases that provide weight-of-evidence classifications for chemical presence in human tissues, in the home environment or in a consumer product present in the home, Maine CDC has evaluated the presence of strong credible scientific evidence for these exposure criteria based on human biomonitoring data from a federal or international governmental agency and/or multiple biomonitoring and exposure studies published in scientific peer-reviewed journals.

PFOS and its salts was previously designated by Maine CDC as a chemical of high concern based on the identification of multiple peer-reviewed scientific publications detailed in the initial identification of chemicals of high concern in 2012 and a subsequent triennial review of the chemicals of high concern list in 2015 (MECDC, 2012 and MECDC, 2015). Because PFOS is considered an emerging chemical with ongoing toxicity evaluations and measurement in humans and the environment, Maine CDC reviewed the most current federal and international authoritative chemical classification database listings for

designating PFOS and its salts as a chemical of high concern, and consequently, as an appropriate candidate for designation as a priority chemical.

This document provides an overview of the evidence for listing PFOS and its salts as a chemical of high concern and proposed listing as a priority chemical. The evidence is organized by the statutorily designated toxicity criteria and exposure criteria. A summary of the individual peer-reviewed studies identified in the 2015 chemical of high concern list review are provided in Appendix 1.

Chemical of High Concern Listing Review

Toxicity criteria

Developmental or reproductive toxicant

In 2015, the Maine CDC reviewed the available scientific peer-reviewed literature for PFOS and determined there were multiple studies with consistent findings of reproductive and developmental toxicity and endocrine disruption in animals (MECDC, 2015, Appendix 1). There were also multiple epidemiological studies identified finding associations between PFOS and reproductive or developmental toxicity as well as endocrine system function (MECDC, 2015, Appendix 1). In addition to these studies identified by the Maine CDC in 2015, the USEPA in 2016 developed a lifetime drinking water health advisory for PFOS based on an adverse developmental outcome in an animal toxicity study (USEPA, 2016). Several other studies demonstrating developmental effects in response to PFOS in animals were identified by the USEPA as candidate studies to derive a drinking water health advisory. While the USEPA Office of Water does not classify chemical toxicity according to a weight-of-evidence approach into a tiered classification system, the USEPA finding of multiple studies showing developmental toxicity is in line with the Maine CDC literature review findings and lends credence to PFOS being a developmental toxicant.

PFOS is now listed by an authoritative international governmental agency under a top-tier classification for reproductive toxicity. The Japanese government maintains a Globally Harmonized System of Classification and Labelling of Chemicals (GHS) database which contains toxicity classifications for hundreds of chemicals. The Japanese GHS database is currently used as a database to identify chemicals that meet the reproductive¹ or human carcinogenesis toxicity criteria for chemical of high concern listing (MECDC, 2012, and MECDC, 2015). In 2017, the Japanese GHS updated the reproductive toxicity listing for PFOS from a Category 1B to a top-tier Category 1A: known human reproductive toxicant listing (Japanese GHS, 2017). Based on this updated classification, there is now strong credible

¹ Japanese GHS (http://www.meti.go.jp/policy/chemical_management/int/files/ghs/h25jgov_en.pdf) reproductive toxicity Category 1: Known or presumed human reproductive toxicant classification -

This category includes substances which are known to have produced an adverse effect on sexual function and fertility or on development in humans or for which there is evidence from animal studies, possibly supplemented with other information, to provide a strong presumption that the substance has the capacity to interfere with reproduction in humans. For regulatory purposes, a substance can be further distinguished on the basis of whether the evidence for classification is primarily from human data (Category 1A) or from animal data (Category 1B).

Category 1A: Known human reproductive toxicant

The placing of the substance in this category is largely based on evidence from humans.

scientific evidence coming from a top-tiered weight-of-evidence determination by an authoritative international government agency that PFOS is a reproductive toxicant.

Human carcinogen

No federal or international governmental agencies have classified PFOS or its salts as a human carcinogen.

Toxicity criteria conclusion

From the previous scientific peer-reviewed literature review in 2015 and the 2017 top-tier reproductive toxicity listing from the Japanese government, Maine CDC considered there to be strong credible scientific evidence that PFOS is a reproductive toxicant and continues to meet the toxicity criteria for listing as a chemical of high concern and therefore criteria for designation as a priority chemical.

Exposure criteria

Present in bodily tissues or fluids

U.S. CDC National Biomonitoring Program, which is designed to be representative of the general U.S. population, continues to detect PFOS in human blood (USCDC, 2017a). In the most recent U.S. biomonitoring results published in 2017 based on specimens collected during 2013-2014, PFOS was measured and detected in blood with a mean serum concentration of 4.99 µg/L (USCDC, 2017b). Since the U.S. CDC began measuring PFOS in its national biomonitoring surveys in 1999, PFOS serum levels have been steadily decreasing (Table 1). This decreasing trend likely reflects the phase-out of PFOS manufacturing, and import and use reductions in the U.S. over this period (USEPA, 2016 and USEPA, 2017). PFOS exposure remains an ongoing concern due to the long half-life in humans and the long-term stability and persistence of PFOS in the environment.

The U.S. CDC National Biomonitoring Program results are representative of levels in children 12 years and older and adults. Several published studies have reported results for PFOS in blood from children less than 12 years old (Olsen et al., 2004; Schecter et al., 2012; Wu et al., 2015). Olsen and colleagues measured PFOS serum levels in 598 children ages 2-12 and found levels ranging from 6.7 to 515 µg/L with a geometric mean of 37.5 µg/L (Olsen et al., 2004). Researchers measured PFOS serum levels in 68 children under the age of 8 from homes in California and found that all children had detectable levels of PFOS in their serum with a geometric mean of 6.28 µg/L (Wu et al., 2015). In Texas, 300 children less than 13 years old had a median serum PFOS level of 4.10 µg/L (Schecter et al., 2012).

In addition to the presence of PFOS in human blood, studies conducted in the United States, Canada, Sweden, Norway, Germany and Japan as well as others have measured and detected PFOS in human breast milk (Kubwabo et al., 2013 and USEPA, 2016).

Table 1. U.S. CDC biomonitoring PFOS serum levels ($\mu\text{g/L}$) for total population sampled (age 12 years and older) from 1999 to 2014.

Survey Years *	Geometric Mean (95% confidence interval)	50th Percentile (95% confidence interval)	95th Percentile (95% confidence interval)
99-00	30.4 (27.1 - 33.9)	30.2 (27.8 - 33.9)	75.7 (58.1 - 97.5)
03-04	20.7 (19.2 - 22.3)	21.2 (19.8 - 22.4)	54.6 (44.0 - 66.5)
05-06	17.1 (16.0 - 18.2)	17.5 (16.8 - 18.6)	47.5 (42.7 - 56.8)
07-08	13.2 (12.2 - 14.2)	13.6 (12.8 - 14.7)	40.5 (35.4 - 47.4)
09-10	9.32 (8.13 - 10.7)	9.70 (8.50 - 10.8)	32.0 (22.6 - 48.5)
11-12	6.31 (5.84 - 6.82)	6.53 (5.99 - 7.13)	21.7 (19.3 - 23.9)
13-14	4.99 (4.50 - 5.52)	5.20 (4.80 - 5.70)	18.5 (15.4 - 22.0)

* Table adapted from the Fourth National Report on Human Exposure to Environmental Chemicals, USCDC, 2017b.

Present in the home environment

PFOS is found in the home environment in indoor dust with several studies finding higher exposure levels for children from indoor dust in the home (Egeghy and Lorber, 2011; Schechter et al., 2012; USEPA, 2016). The literature review conducted by the USEPA in developing a PFOS drinking water health advisory found several studies that measured and detected PFOS in indoor dust from homes in the United States (USEPA, 2016). Maine CDC also identified several studies that detected PFOS in indoor house dust. (MECDC, 2015, Appendix 1).

Exposure criteria conclusion

In addition to the U.S. CDC biomonitoring studies, there are multiple studies published in peer-reviewed scientific journals demonstrating that PFOS is found in humans, particularly blood and human breast milk. There are also multiple studies that found PFOS in the home environment in indoor dust. Taken together, there is strong credible scientific evidence that PFOS is present in humans and the home environment.

References

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Appendix 1

2015 Maine CDC Chemical of High Concern listing review - inclusion criteria for Perfluorooctane sulfonic acid (PFOS) and its salts (CAS 1763-23-1)

Toxicity criteria for reproductive and developmental toxicity

Animal studies:

1. Butenhoff, J.L., Ehresman, D.J., Chang, S.C., Parker, G.A., Stump, D.G. (2009). Gestational and lactational exposure to potassium perfluorooctanesulfonate (K+PFOS) in rats: developmental neurotoxicity. *Reproductive Toxicology* 27 (3-4):319-30.
2. Chang, S.C., Ehresman, D.J., Bjork, J.A., Wallace, K.B., Parker, G.A., Stump, D.G., Butenhoff, J.L. (2009). "Gestational and lactational exposure to potassium perfluorooctanesulfonate (K+PFOS) in rats: toxicokinetics, thyroid hormone status, and related gene expression. *Reproductive Toxicology* 27 (3-4):387-99.
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Human studies:

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