



The following exposure assessment document was prepared August 20, 2019, by W. L. Gore & Associates for use by its associates, customers, and other interested parties to assist in fostering a better understanding of Gore's materials and their attributes. This document and the information included are specific to Gore's moisture barrier component of structural firefighting gear. The assessment explains potential risks of cancer associated with exposure to non-polymer PFAS trace residuals that may be found in the Gore component when wearing the finished gear for its intended use in firefighting applications.

An exposure assessment is a science-based process to evaluate the potential of adverse health effects in humans who may be exposed to a specified chemical, taking into account the potential pathway of exposure (e.g. oral ingestion, inhalation, skin contact), potential volume, properties of the material, and standard human/biological factors. Gore utilized standard EPA methodologies and tools to conduct the assessment.

Summary of PFOA Exposure Assessment for Pre-2013 Gore Component in Firefighting Gear

Summary

After a multi-year technical program, the Gore Fabrics Division succeeded in eliminating PFOA from its supply chain and products in 2013. Because firefighting gear can be used for ten years, an updated analysis incorporating EPA's 2016 human equivalent dose for cancer effects was conducted to estimate cancer risks associated with potential exposures to PFOA for firefighters wearing a complete kit of turnout gear and the pre-2013 Gore Components in turnout gear. The analysis shows that these potential exposures and associated risks of cancer effects are insignificant.

Exposure Assessment Method

The starting point for this analysis was an exposure assessment conducted by Washburn, *et al.* (2005)¹. Washburn calculated exposures and risks for perfluorooctanoate (PFO⁻) in selected consumer articles manufactured with fluoropolymers or fluorotelomer-based products. Exposures and risks were calculated using a series of standard equations for several routes of exposure, including dermal contact, hand-to-mouth contact, ingestion of dust, and inhalation of particulates. Washburn estimated exposures for reasonable maximum exposure (RME) and more typical exposure (MTE) scenarios based on selection of values for the factors in the exposure equations.

One of the scenarios in the Washburn assessment, the "Professional" scenario, assessed exposures for persons who worked with treated articles in an occupational setting, such as tailoring. The assumptions and data for the Washburn "Professional" scenario were the starting point in this document for two new occupational scenarios for the Gore Components in firefighter's turnout gear.

(1) "Gore Component Skin Only Scenario" assumes that the PFOA in the Gore Component is in contact with the firefighters' skin at the neck and wrists, which represents the typical garment construction.

(2) "Gore Component Conservative Maximum Firefighter Exposure" Scenario assumes that the PFOA in the Gore Component is transferred through the gear when saturated with water or perspiration and is therefore in contact with a significant portion of the firefighter's body.

¹ Washburn, ST, TS Bingman, SK Braithwaite, RC Buck, LW Buxton, HJ Clewell, LA Haroun, JE Kester, RW Rickard, and AM Shipp. 2005. Exposure assessment and risk characterization for perfluorooctanoate in selected consumer articles. *Environ. Sci. Technol.* 39: 3904-3910.



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The exposure assessment is based on certain assumptions that are conservative, meaning the exposure calculated is likely an overestimate of actual conditions. One major conservative assumption made is that 100% of any PFOA found in the garment is bioavailable every day for the garment's 10-year life. In other words, the amount of PFOA assumed to come from the garment never declines over the 10-year life of the garment.

Regulatory Context

For cancer effects from chemical exposures such as PFOA, regulators typically find an acceptable Margin of Exposure (MOE) to be 100². A MOE is a "safety buffer"; it represents the margin between the dose at which a toxic effect was observed ("point of departure") and the predicted exposure dose. The higher the MOE, the less likely a chemical is to pose an unreasonable risk. In relative terms, EPA has said that if the MOE indicates that a particular toxicity effect level is 10,000 times higher than the expected exposure dose there is *little concern* that concentrations will reach levels where toxicity is possible². EPA considers a MOE of 100 or more to be a low risk².

Conclusion

The analysis shows that the margins of exposure (MOE) for PFOA from pre-2013 Gore Components in turnout gear range from 28,000,000 to 1,500,000,000 using the 2016 EPA quantitative cancer risk assessment human equivalent dose (**0.58** mg PFOA/kg body weight/day) associated with testicular cancer³. Using the Washburn 2005 PFOA Health Benchmark of **5.1** mg PFOA/kg body weight/day, MOEs for cancer effects range from 240,000,000 to 13,000,000,000 for the Gore Component scenario. Therefore, the MOEs mean that the estimated career exposures from wearing firefighting turnout gear with Gore Components are many millions higher than an MOE of 100, using either the 2005 or the 2016 EPA benchmark doses for risk characterization. Thus, these potential exposures and associated risks of cancer effects are insignificant.

A handwritten signature in black ink that reads "Barbara J. Henry".

Barbara J. Henry, Ph.D. / August 20th, 2019
Toxicologist
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² U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, EPA-748-B 12-00 I, Sustainable Futures / P2 Framework Manual 2012.

³ EPA selected the testicular cancer dose level to be protective of all tumor types. See United States Environmental Protection Agency, Office of Water, EPA 822-R-16-005, Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA), May 2016.