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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.

Exposure Assessment and Cancer Risk Characterization for Firefighters from Non-Polymeric PFAS Residuals in Gore Components Used 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. PFOA alternatives are used by manufacturers to polymerize fluoropolymers purchased by Gore. Additionally, durable water repellency ("DWR") treatments based on short-chain side chain fluorinated polymers are now in use. This exposure assessment, incorporating human equivalent dose for cancer effects from the Residual Non-Polymeric PFAS[1], was conducted to assess the potential exposures and associated risks of cancer effects for firefighters from the Gore Components incorporated into a complete kit of turnout gear. As with the previous assessment[2], this assessment shows that the potential exposures and associated risks of cancer effects from PFOA alternative and non-polymeric perfluoroalkyl substances in Gore Components are insignificant[3].

Details

The starting point for this analysis was an exposure assessment conducted by Washburn, *et al*. (2005)[4]. 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.

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[1] In this document, the residual PFOA alternatives from the fluoropolymers and the residual non-polymeric PFAS from the DWR are collectively referred to as "Residual Non-Polymeric PFAS".

[2] Because firefighting gear can be used for ten years, an updated analysis of the potential exposures and associated risks of cancer effects from PFOA in the pre-2013 Gore Components in turnout gear was conducted. That analysis shows that the potential exposures and associated risks of cancer effects from PFOA are insignificant.

[3] The term "insignificant" is used here in the context of human health hazard -the capacity to cause adverse effects on human health or the environment. The calculated total hypothetical lifetime average intake was less than the EPA's draft chronic reference dose (RfD). The EPA IRIS website defines reference dose as "An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." Therefore, if daily exposure at the RfD during a lifetime presents no appreciable risk, exposures below the RfD can be said to be insignificant.

[4] 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.

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 Residual Non-polymeric found in the Gore Component is in contact with the firefighters' skin at the neck and wrists only, which represents the typical garment construction.

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

For cancer effects from chemical exposures such as PFOA, regulators typically find an acceptable Margin of Exposure (MOE) to be 100[5]. 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 possible[5]. EPA considers a MOE of 100 or more to be a low risk[5].

The most conservative toxicity endpoint from the data on the Residual Non-polymeric PFAS, including (but not limited to) those found in Gore components to firefighting gear, was selected for the MOE calculation. The mass of all the various Residual Non-polymeric PFAS was summed. This assessment assumes that these Residual Non-polymeric PFAS all have the same toxicity and that their concentrations "recharge daily" so that initial concentrations in the gear never decreases with use even over 25 years, adding to the conservatism of the assessment.

This analysis shows that the margins of exposure (MOE) for Residual Non-polymeric PFAS in Gore components in turnout gear range from 5,000 (Gore component maximum exposure) to 210,000 (Gore component skin only). This means that the estimated career exposures from wearing firefighting turnout gear with Gore components are 50 to 2,100 times higher than an MOE of 100 using the lowest safe human equivalent dose. Therefore, the potential exposures and associated risks of cancer effects from PFOA alternatives and Residual Non-polymeric PFAS in Gore Components are insignificant[6].

Barbara J. Henry, Ph.D. / August 20th, 2019
Toxicologist
W. L. Gore & Associates, Inc.

[5] U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, EPA-748-B 12-00 I, Sustainable Futures / P2 Framework Manual 2012.

[6] The term "insignificant" is used here in the context of human health hazard - the capacity to cause adverse effects on human health or the environment. The calculated total hypothetical lifetime average intake was less than the EPA's draft chronic reference dose (RfD). The EPA IRIS website defines reference dose as "An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." Therefore, if daily exposure at the RfD during a lifetime presents no appreciable risk, exposures below the RfD can be said to be insignificant.