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Office of Pollution Prevention and Toxics
US EPA
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Washington, DC 20460-0001

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TSCA 8(E) SUBSTANTIAL RISK SUPPLEMENTAL NOTICE ON: Perfluorooctane sulfonate (PFOS), perfluorohexanesulfonate (PFHS), N-methyl-N-acetyl-perfluorooctanesulfonamide (M570)
Reference 8EHQ -1180-373, 374

Dear Sir:

3M has received the draft report for a repeated dermal contact absorption/toxicology study in rats conducted with four mill-applied and aftermarket carpet/fabric/upholstery protector products that 3M ceased manufacturing as part of its perfluorooctanyl chemistries phase-out. The attachment hereto provides the composition for each of these products. The results indicate that repeated daily dermal contact over a 28-day period with these formulations, in the liquid state or after application and drying on gauze, resulted in increases above background controls in the concentration of perfluorooctanesulfonate (PFOS) in liver and serum (all but one product), and of perfluorohexanesulfonate (PFHS) and N-methyl-N-acetyl-perfluorooctanesulfonamide (M570) in serum (not measured in liver) for certain products. M570 is an intermediary metabolite of a manufacturing residual (N-methyl-perfluorooctanesulfonamido ethanol (N-MeFOSE)) present in certain products, which can be further metabolized to PFOS. No toxicity attributable to any sample was evident in this study, either on the skin, or systemically.

The study was conducted by the Fraunhofer Institute of Toxicology, Hannover, Germany. Cotton gauze patches (~1 square inch) to which the liquid test material had previously been applied and allowed to dry, or liquid samples (0.1 ml) applied to gauze without drying, were applied to the shaved dorsal skin of male and female rats in a semi-occluded fashion for six hours each day for up to 28 days. The preparation of the samples dried on cotton gauze involved saturating the gauze with liquid product, wringing the saturated gauze through a roller press at 100 pounds pressure and allowing the wrung gauze to air dry at room temperature. As such, the application of product to gauze did not precisely

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mimic normal application on carpet, fabrics and upholstery but was expected to represent the higher end of normal product application. The liquid samples were adjusted to provide approximately the same amount of product solids as present in the dried samples applied to fresh gauze in a volume of 0.1. Fresh treated patches were applied each day. Pairs of rats, 2/sex, were sacrificed on days 4, 14, 28 and 42 for pathology and determination of PFOS level in liver and PFOS, PFHS, and M570 levels in serum (selected time points). Rats sacrificed on day 42 were treated for the first 28 days followed by a 14-day period without treatment.

Repeated dermal contact under semi-occlusive conditions with all but one of the test samples resulted in consistently quantifiable serum and liver concentrations of PFOS that exceeded levels in control rats exposed to gauze patches moistened only with saline. The exception was a mill-applied carpet protector. With that product, only one male exposed to the liquid product for 28 days, and one female exposed to previously treated and dried gauze patches for 28 days showed liver PFOS levels at close to the level of quantitation (LOQ) of 10 ppb. All other samples were below the LOQ. M570 was detected at consistently quantifiable levels in serum from exposure to only one of the product samples. This sample also yielded trace levels (about 1 ppb) of PFHS in serum of rats exposed daily for 28 days. PFHS was also detected at higher levels (up to about 1 ppm) in the serum of animals exposed to the product that also yielded the highest liver (up to 7-10 ppm) and serum (up to 1 ppm) levels of PFOS.

3M will submit the final report to EPA when available. Because of differences in the nature of the treated fabric (cotton gauze v. carpet or upholstery) and conditions of dermal contact, these data can not be used quantitatively to determine human exposures to PFOS, PFHS and N-MeFOSE from contact with treated materials. These data do, however, indicate that dermal absorption of PFOS, PFHS and N-MeFOSE from contact with these materials is possible. As indicated above, 3M discontinued the manufacture of these products for commercial sale as part of 3M's phase out of its perfluorooctanyl chemistries.

Please contact Dr. John L. Butenhoff (651-733-1962) if you have any questions or if we can provide additional information.

Sincerely,

Katherine E. Reed
Staff Vice President, Environmental Technology and Safety Services

Enclosure