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EPA East – Room 6428 Attn: Section 8(e)
Office of Pollution Prevention and Toxics
US EPA
1200 Pennsylvania Avenue NW
Washington DC 20460-0001

Re: TSCA 8(e) Substantial Risk Notice: Supplemental to Docket No. 8EHQ-0598-373; Sulfonate-based and Carboxylic-based Fluorochemicals

To whom it may concern:

3M recently received a draft final report from an oral (gavage) developmental neurotoxicity and thyroid function study in rats conducted on potassium perfluorooctane sulfonate (PFOS). The objective of this study was to determine the potential of PFOS to induce neurotoxic effects in offspring following exposure of the mother to PFOS during gestation and lactation, and to determine the effects of exposure on maternal and neonatal thyroid status. Exposure to PFOS during gestation and lactation did not result in any neurotoxic effect in F1-generation offspring at doses of 0.1 or 0.3 mg/kg/day and showed at the highest dose of 1.0 mg/kg/day only a very limited, transient effect on motor activity and habituation in males.

Time-mated female rats were administered potassium PFOS daily by oral gavage at dose levels of 0.1, 0.3, or 1.0 mg/kg/day during gestation and through lactation day (LD) 20. Functional observation battery (FOB), acoustic startle response, locomotor activity, and learning and memory evaluations were performed. In addition, brain weight and potential neuropathological evaluations were conducted, and indicators of physical development (balanopreputial separation and vaginal patency) were evaluated. Thyroid structure and function were evaluated via microscopic examination of thyroids, thyroid cell proliferation assay, and analysis of TSH levels.

Functional observational battery parameters, startle responsiveness, swimming ability, learning and memory and mean age and weight at attainment of balanopreputial separation and vaginal patency in the F_1 males and females during the pre- and/or post-weaning periods were unaffected by maternal treatment with PFOS. In addition, there were no PFOS-related clinical or internal findings or changes in brain weight, length, or width in F_1 males or females. PFOS-related effects were limited to postnatal day (PND) 17, where an increase in total and ambulatory motor activity counts and a decrease in the number of rats habituating to the test environment were observed in males in the 1.0 mg/kg/day group as compared to the concurrent control group. There were no other test article-related effects on motor activity in either sex at any dosage level on PND 13, 17, 21 or 61. There were no changes in TSH or thyroid gland histology that were attributable to PFOS. Maternal body weights were decreased with statistical significance in the

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1.0 mg/kg/day dosage group relative to controls during the lactation period. This indicates that the highest dose chosen was appropriately effective in producing an effect in maternal rats.

Although these data do not meet the 'substantial risk' reporting threshold, we recognize the ongoing work by U.S. EPA to assess fluorochemicals. Therefore, we are placing these results in the 8(e) docket as a supplement to previous submissions.

The in-life portion of this study is complete and a draft final report has been produced. The final report is pending inclusion of results from analysis of pharmacokinetic samples. The final report will be forwarded to the EPA once it is received.

If you have any questions or need additional information, please contact Deanna Luebker at (651) 737-1374.

Sincerely,

Katherine E. Reed

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Staff Vice President, Environmental, Health and Safety Operations