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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: Docket No. 8EHQ-07-16721

To Whom It May Concern:

3M recently finalized a 90-day study and toxicokinetic (TK) evaluation conducted on [*Fluorinated surfactant salt*]. Results of this study and TK evaluation are not 8(e) reportable; however, 3M is submitting them to supplement previous submissions on this chemical, most specifically a 28-day study in rats submitted to the EPA in May of 2007.

Results of the 28-day study demonstrate a statistically significant increase in mean liver weights in mid and high dose (30 and 100 mg/kg) males as compared to controls at the end of the 28-day treatment period. Although the morphological changes of the liver were deemed to be adaptive, the magnitude of the increase in liver weight at these dose levels was considered adverse.

In the 90-day study in rats, the No Observed Adverse Effect Level (NOAEL) was determined to be 10 mg/kg/day for males and 100 mg/kg/day for females, the high dose for each sex. Minimal or slight liver hypertrophy was observed in most males at 10 mg/kg/day. This finding was coupled with slightly elevated aspartate aminotransferase activity. This effect is commonly observed in situations of adaptive response associated with exposure to xenobiotics. These results, thus, provide evidence supporting the adaptive nature of the liver effects seen in the 28-day study.

Results of the TK evaluation demonstrate the test material is well absorbed orally, cleared more slowly from plasma in males than females, and not preferentially distributed in the liver. These results are in agreement with a previously conducted 5-day oral study in rats where the terminal serum elimination half live of the test material was determined to be less than 24 hours in females and approximately 30-40 hrs in males.

Please contact Deanna Luebker at 651-737-1374 or [djluebker@mmm.com](mailto:djluebker@mmm.com) if you have any questions or if we can provide additional information.

Sincerely,

*Jean B. Sweeney (H&S)*

Jean B. Sweeney  
Staff Vice President, Environmental Health and Safety Operations

Company Seal

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**Substantiation Questions**

1. Is your company asserting this confidential business information (CBI) claim on its own behalf? If the answer is no, please provide company name, address and telephone number of entity asserting claim.

*Yes, the CBI claim is on behalf of 3M.*

2. For what period do you assert your claim(s) of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point.

*The period of time for confidentiality should be indefinite because 3M plans to manufacture the substance for use in making 3M products for an indefinite period with continued reliance on the competitive advantage it has in the confidential nature of said substance.*

3. Has the information that you are claiming as confidential been disclosed to any other governmental agency, or to this Agency at any other time? Identify the Agency to which the information was disclosed and provide the date and circumstances of the same. Was the disclosure accompanied by a claim of confidentiality? If yes, attach a copy of said document reflecting the confidentiality agreement.

*Yes, the confidential information, chemical identity, has been submitted to [ ].*

4. Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming CBI.

*The measures taken to prevent undesired disclosure include standard 3M security procedures, such as [ ].*

5. If anyone outside your company has access to any of the information claimed CBI, are they restricted by confidentiality agreement(s). If so, explain the content of the agreement(s).

*Yes, [ ].*

6. Does the information claimed as confidential appear or is it referred to in any of the following:

a. Advertising or promotional material for the chemical substance or the resulting end product;

*No*

b. Material safety data sheets or other similar materials (such as technical data sheets) for the substance or resulting end product (include copies of this information as it appears when accompanying the substance and/or product at the time of transfer or sale);

*No*

c. Professional or trade publications; or

*No*

d. Any other media or publications available to the public or to your competitors.

*No*

If you answered yes to any of the above, indicate where the information appears, include copies, and explain why it should nonetheless be treated as confidential.

*Not applicable, the chemical identity appears as a masked name on the MSDS. The material is an internally used chemical and not sold outside of 3M*

7. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? If so,

14. Is the substance or any information claimed CBI the subject of FIFRA regulation or reporting? If so, explain.

No

**3M Contact:**

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