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MR# 318283

March 31, 2009



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Via Federal Express

United States Environmental Protection Agency - East  
Attn: TSCA Section 8(e)  
Room 6428  
1201 Constitution Avenue, NW  
Washington, DC 20004



Subject: Notice in Accordance with Section 8(e): Results of a Subchronic Inhalation Study in Wistar Rats with Copolymer Containing Acrylates and Acrylamide

Dear Sir/Madam:

BASF Corporation is submitting information on results of a Subchronic 90-day Inhalation Study in Wistar Rats with Copolymer Containing Acrylates and Acrylamide, conducted by BASF SE, Ludwigshafen, Germany. The test substance is a personal care ingredient.

The study was carried out in accordance with the requirements of the international guideline:

- OECD Guidelines for Testing of Chemicals, Guideline 413

**Scope of the Examination**

Ten male and ten female Wistar rats per test group were nose-only exposed to liquid aerosols of the test substance for 6 hours a day on 5 days per week for 90 days (65 exposures). The target concentrations of the test groups were 0, 1, 3 and 10 mg/m<sup>3</sup>. The liquid aerosol atmosphere was generated by an atomizer.

**The following is a summary of the most relevant results:**

The measured concentrations were 1.0, 3.0 and 10.0 mg/m<sup>3</sup>. The mass median aerodynamic diameters ranged between 0.2 and 0.8 µm.

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At 10 mg/m<sup>3</sup>, slight neutrophilia in the female animals was observed during the hematological examinations. During necropsy, increased absolute (+109 % for males, +124 % for females) and relative (+125 % for males, + 118 % for females) lung weights were noted. Light microscopic examination revealed slight to extreme severe alveolar histiocytosis, minimal to moderate broncho-alveolar hyperplasia in the lung and lympho-reticulocellular hyperplasia in the mediastinal lymph nodes.

At 3.0 mg/m<sup>3</sup>, increased absolute (+97 % for males, +84 % for females) and relative lung weight (+114 % for males, +82 % for females) were observed during necropsy. The histological findings were similar to those described above but of less severity.

At 1 mg/m<sup>3</sup>, relative lung weight (+12 % for males, + 9 % for females) was still increased, minimal to slight broncho-alveolar hyperplasia was still present in most of the test animals. Although these findings were of minimal grade, they are considered to be treatment-related adverse effects at concentration as low as 1 mg/m<sup>3</sup>. Therefore, under the described study conditions, the No Observed Adverse Effect Concentration (NOAEC) is below 1 mg/m<sup>3</sup>.

BASF Corporation understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note that a confidential version of this letter is enclosed, treating the chemical identities as confidential business information.

The information considered confidential is highlighted, in accordance with U.S. EPA policy. The non-confidential name can be referred to as "Copolymer Containing Acrylates and Acrylamide."

A confidentiality substantiation questionnaire is being submitted for this substance.

Please send all correspondence related to this submission to the attention of Janet Cerra. If you have any questions, please call (973) 245-6693.

Sincerely,

*Janet Cerra*

Janet Cerra

Enclosures

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