Bayer MaterialScience

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March 8, 2010

Product Safety & Regulatory Affairs and
Management Systems
Bayer MaterialScience LLC
100 Bayer Road
Pittsburgh, PA 15205-9741

CERTIFIED MAIL

Document Control Officer 8(e) Coordinator
U. S. Environmental Protection Agency – East
Confidential Business Information Center
Mail Code: 7407M
1200 Pennsylvania Avenue. N.W.
Washington, DC 20460

Subject: TSCA 8(e) Submission

Dear Sir:

Bayer MaterialScience is submitting 2-Week Inhalation Study in Wistar Rats (Exposure 6 h/day, 5 days/week on 1½ consecutive weeks).

Bayer MaterialScience LLC is submitting these data in accordance with EPA's interpretation of the requirements of TSCA § 8(e) as expressed in agency guidance. However, BMS has not determined whether these data actually disclose a substantial risk of injury to health or the environment associated with the chemical substance or mixture.

Please contact me if you have any questions.

Sincerely,

Attachment

8EHQ-10-17860

CONFIDENTIAL BUSINESS INFORMATION

COMPOUND: 1,5-naphthylene Diisocyanate (NDI)

STUDY TITLE: 2-Week Inhalation Study in Wistar Rats (Exposure 6 h/day, 5 days/week on 1½ consecutive weeks)

A 1½-week pilot inhalation study was conducted on NDI (CAS No. 3173-72-6) in accordance with OECD Guideline 412 (Repeated Dose Inhalation Toxicity: 28-Day or 14-Day study) and 1998 OPPTS guidelines. Groups of 10 male Wistar rats were exposed to aerosol concentrations of 0, 0.19, 1.1, 4.8, and 19.0 mg/m^3 for 6 hr/day on 5 days/week for 1½ weeks. MMADs were in the range of 2.5 to 2.7 μm. Five rats per group were sacrificed on the day after the 9th exposure; the remaining animals were sacrificed after an additional 2 weeks without exposures.

Endpoints included body weights (twice weekly and at sacrifice) and clinical observations (daily). Animals were sacrificed at the end of exposures and after the recovery period. At sacrifice, lungs were lavaged, animals were necropsied, 6 organs were weighed, and several tissues related to the respiratory tract were taken for histopathology.

Rats exposed to 0.19 or 1.1 mg/m^3 did not have effects on clinical signs or body weights while those exposed to 4.8 or 19.0 mg/m^3 had labored breathing, breathing sounds, and other changes. Loss of body weight and marked respiratory distress occurred at 19.0 mg/m^3, and 2 of 10 animals died in this group near the end of exposures. Changes in BAL parameters (protein, γ-GT, alveolar macrophages, PMNs) started to occur at 1.1 mg/m^3 and were more pronounced at higher concentrations. Epithelial changes in the nose (epithelial "alteration", squamous metaplasia, atrophy and/or degeneration) occurred at 4.8 mg/m^3 and above; focal inflammatory infiltrates occurred at 1.1 mg/m3. Concentration-related epithelial changes in the larynx occurred in all treated groups. Epithelial changes continued deeper into the lungs with hypertrophy in the bronchiolo-alveolar airways. The investigator reports all effects showed a clear trend toward recovery during the non-exposure phase. Excluding the larynx, the NOAEC was 0.19 mg/m^3.