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Bayer MaterialScience

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Bayer MaterialScience LLC  
100 Bayer Road  
Pittsburgh, PA 15205-9741  
Phone:  
FAX:  
e-mail:

8EHQ-0411-18330A

88110000214s

CONTAINS TSCA CONFIDENTIAL  
BUSINESS INFORMATION



**By Certified Mail**

TSCA Confidential Business Information Center (7407M)  
EPA East – Room 6428 Attn: Section 8(e)  
U. S. Environmental Protection Agency  
1200 Pennsylvania Avenue. N.W.  
Washington, DC 20460



Subject: TSCA § 8(e)  
Test Substance: 1,5-Naphthylene Diisocyanate (NDI) CAS# 3173-72-6

Dear Sir or Madam:

Bayer MaterialScience LLC (the “*Company*”) is submitting a 90-day inhalation study with 1-month recovery period in Wistar rats of the Test Substance, which the Company imports, processes, and distributes in the United States.

The Company is submitting these data in accordance with our understanding of EPA’s interpretation of the requirements of TSCA § 8(e) as expressed in agency guidance. However, the Company 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.

This submission contains TSCA confidential business information (“*CBI*”). Accordingly, the Company is providing both original and redacted versions of this submission to EPA, along with the attached justification of the Company’s CBI claims. In keeping with recent guidance from EPA, the Company is not claiming the chemical identity as CBI.

**Company Sanitized**

Please contact me if you have any questions.

Sincerely,

Attachment

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**TEST SUBSTANCE:** *CAS# 3173-72-6 1,5-Naphthylene diisocyanate (NDI)*

**STUDY:** **90-day inhalation study with 1-month recovery period in Wistar rats**

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A study was performed to assess the subchronic inhalation toxicity of the Test Substance.

The study was conducted in accordance with the OECD guideline 413.

Groups of Wistar rats (10/sex) were exposed head-only to mean aerosol concentrations of 0, 0.065, 0.25, 1.02, and 3.96 mg/m<sup>3</sup> for 6 hr/day, 5 days/wk for 13 weeks. Mass median aerodynamic diameters were in the range of 2.1 – 2.6 µm. Endpoints included clinical signs (5 days/wk), body weights (twice weekly), food and water consumption, reflexes, ophthalmology, and rectal temperature during the biophase. Clinical chemistry, hematology, urinalysis, gross pathology findings at necropsy, organ weights, and histopathology were evaluated at the end of the exposure phase. Additional groups of rats (10/sex) were exposed to 0 or 3.96 mg/m<sup>3</sup> and observed for reversibility of effects 4 weeks following 90 days of exposure.

Only rats exposed to 3.96 mg/m<sup>3</sup> had treatment-related clinical signs including bradypnea, irregular and labored breathing, dyspnea, breathing sounds, stridor, reduced motility, limp, high-legged gait, cyanosis and bloated abdomen. No significant effects were observed on body weight, food or water consumption, reflexes, body temperature, ophthalmology, hematology, clinical chemistry (except increased bilirubin at 3.96 mg/m<sup>3</sup>), or urinalysis. Weights of adrenals, brain, epididymides, kidneys, liver, ovaries, spleen, testes, or thymus were not affected. Lung weight was significantly increased at 1.02 and 3.96 mg/m<sup>3</sup>. Heart weights were significantly increased in females at 3.96 mg/m<sup>3</sup>. These weight changes were not fully reversed during the 4-week postexposure period. Histopathology at the two highest concentrations included findings of slight to minimal severity at the portal of entry. The principal findings include changes to the olfactory and respiratory epithelium of the nasal cavity (epithelial degeneration and/or atrophy, goblet cell hyperplasia and increased inflammatory infiltrates), irritant related changes to the larynx (eg epithelial squamous metaplasia), and bronchiolo-alveolar hypercellularity, minimal septal thickening, inflammatory infiltrates and increased alveolar macrophages with foamy appearance in the lungs. No effects were reported for animals exposed to 0.25 or 0.065 mg/m<sup>3</sup> except for laryngeal epithelial squamous metaplasia.

After the recovery period, slight to minimal degeneration and/or atrophy of the olfactory epithelium was still apparent in the nasal cavity. In addition, unusual nerve-like structures were observed in the epithelium and neuronal degeneration of nerve bundles was seen in the lamina propria. In the lungs, minimal hypercellularity of the bronchiolo-alveolar region and increased macrophages were still seen. Histopathology changes of the pharynx, larynx and trachea fully recovered. Female rats tended to be more susceptible than males. The NOAEL was 0.25 mg/m<sup>3</sup>.