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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 TSCA Section 8(e): Results of a Subacute 28-Day Liquid Aerosol Inhalation Study in Wistar Rats with Protectol HT, (1,3,5-Tris-(2-hydroxyethyl)-1,3,5-hexahydrotriazine), (CAS No. 4719-04-4)

Dear Section 8(e) Coordinator:

BASF Corporation is submitting results of of a Subacute 28-Day Liquid Aerosol Inhalation Study in Wistar Rats (CrI:WI(Han)) with Protectol HT aerosols, (1,3,5-Tris-(2-hydroxyethyl)-1,3,5-hexahydrotriazine), (CAS No. 4719-04-4), conducted by BASF SE, Ludwigshafen, Germany. The substance is a biocide and an industrial chemical.

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

- OECD Guidelines for Testing of Chemicals, Guideline 412/413
- Commission Regulation (EC) No 440/2008

**Scope of the Examination**

Ten male and ten female Wistar rats per test group were nose-only exposed to liquid aerosol of HHT for 6 hours a day, 5 days a week for 4 weeks (total 20 exposures). The initially targeted concentrations were 3, 10, 30 and 100 mg/m<sup>3</sup>. A concurrent control group was exposed to clean air.

The examination of the animals comprised daily clinical observation, detailed clinical observation in standard area, ophthalmology, clinical pathological and hematological investigations, gross necropsy and histopathological examination according to OECD test guideline 413.

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

**Test group 4 (100 mg/m<sup>3</sup>):**

- Severe clinical findings including laboured breathing and respiratory noise
- Premature death of 5 out of 10 male animals
- For animal welfare reason, the exposure was stopped after study day 6.

**Test group 3 (30 mg/m<sup>3</sup>):**

- Larynx: squamous metaplasia and hyperplasia with erosion/ulceration, necrosis of cartilage, inflammation
- Lung: epithelial degeneration, BALT increase
- Nasal cavity: squamous metaplasia
- Trachea: Squamous metaplasia

Same findings were observed at test group 2 and 1(10 and 3 mg/m<sup>3</sup>) with lower incidence and severity.

Under the described study conditions, No Observed Adverse Effect Concentration (NOAEC) could not be established.

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

If you have any questions, please contact the undersigned at (973) 245-6693.

Sincerely,

*Janet Cerra*

Janet Cerra  
Product Regulatory Center of Expertise  
North America

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From: (973) 245-6693  
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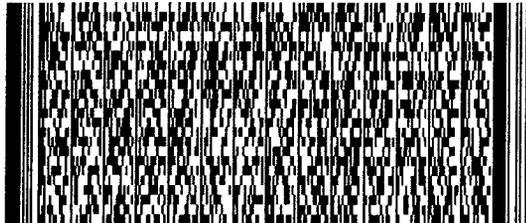
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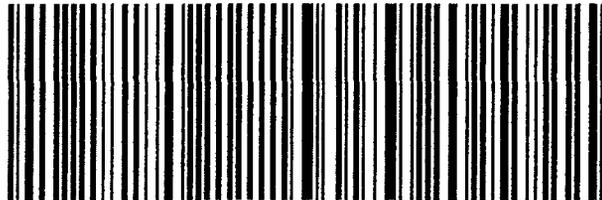
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