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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 Repeated Dose 28-Day Oral Toxicity Study in Male Wistar Rats with Tinuvin 144, (Propanedioic acid, [[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]butyl-, bis(1,2,2,6,6-pentamethyl-4-piperidinyl) ester) (CAS No. 63843-89-0)
Initial Submission: 8EHQ-11-18464

Dear Section 8(e) Coordinator:

BASF Corporation is submitting results of of a Repeated Dose 28-Day Oral Toxicity Study in Male Wistar Rats [Cr:WI(HAN)] with Tinuvin 144, (Propanedioic acid, [[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]butyl-, bis(1,2,2,6,6-pentamethyl-4-piperidinyl) ester) (CAS No. 63843-89-0) conducted by BASF SE, Ludwigshafen, Germany. The substance is a light stabilizer and antioxidant in adhesives and sealants.

The aim of the study was to determine the toxicological profile of the test substance including the target organs and the "no observed adverse effect level" (NOAEL) of the test substance after 28-day oral administration in the male rat.

The test substance was administered by gavage to groups of 5 male Wistar rats for up to 28 days. The concentration levels were 0, 5, 25, 50 and 75 mg/kg body weight/day. Food and water consumption as well as body weights were determined once a week.

On study day 14, the high-dose group was sacrificed moribund because of severe clinical findings. On study day 22, the high mid-dose group (50 mg/kg bw/d) was sacrificed moribund because of severe clinical findings. At necropsy, these animals were only assessed by gross pathology. On study day 28, all surviving animals were sacrificed and examined by gross pathology. In addition, examination of liver, spleen and thymus weights as well hematology parameters were performed. Histopathology was performed for jejunum, liver, mesenteric lymph nodes and spleen at dose levels of 25 and 5 mg/kg bw.

Significant adverse effects relating to signs of clinical toxicity (including mortality) and clinical pathology observations for this study have already been submitted under TSCA 8(e) Document Number 8EHQ-11-18464.

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The following is a summary of the most relevant results

75 mg/kg body weight/day (treatment of 14 days):

- All male animals were sacrificed moribund on study day 14.
- Thickening of duodenum wall in all animals
- Enlarged liver in all animals
- Enlarged liver lymph node in 1 animal
- Reduced prostate size in all animals
- Reduced size of seminal vesicle in all animals
- Reduced thymus size in 3 animals

- **Clinical Pathology and Histopathology were not performed.**

50 mg/kg body weight/day (treatment of 22 days):

- All male animals were sacrificed moribund on study day 22.
- Thickening of duodenum wall in all animals
- Enlarged liver in all animals
- Enlarged liver lymph node in 2 animal
- Enlarged spleen in 4 animals
- Reduced prostate size in all animals
- Reduced size of seminal vesicle in all animals
- Reduced thymus size in 1 animal

- **Clinical Pathology and Histopathology were not performed.**

25 mg/kg body weight/day (treatment of 28 days):

- Reduced body weight and body weight gain when compared to control animals
- Thickening of jejunum wall in all animals
- Enlarged liver in 1 animal
- Enlarged mesenteric lymph nodes in all animals
- Enlarged spleen in 2 animals
- Foam cell aggregates, diffuse, in jejunum of all animals
- Foam cell aggregates, (multi)focal, in liver of all animals
- Granulomatous inflammation in mesenteric lymph nodes of all animals
- Granulomatous inflammation in spleen in 2 of 5 animals; foam cell aggregates in 3 of 5 animals



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5 mg/kg body weight/day (treatment of 28 days):

- Foam cell aggregates, diffuse, in jejunum of all animals
- Foam cell aggregates, (multi)focal in liver in 2 of 5 animals
- Granulomatous inflammation in mesenteric lymph nodes in 3 of 5 animals

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

/

1271st Letter.doc

From: (973) 245-6693
Janet Cerra
BASF
100 Campus Drive

Origin ID: LKKA



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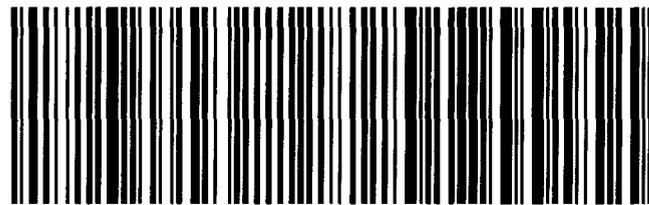
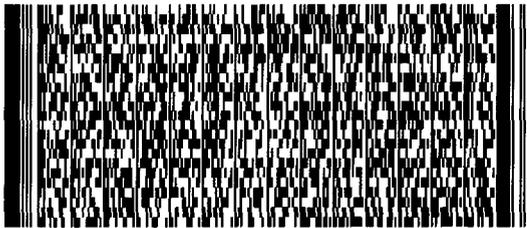
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