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June 26, 2012



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 an OECD 421
Reproduction/Developmental Toxicity Screening Test in Wistar Rats with Propanedioic
acid, [[3,5-bis(1,1-dimethylethyl)-4- hydroxyphenyl]methyl]butyl-, bis(1,2,2,6,6-
pentamethyl-4- piperidiny) ester (CAS No. 63843-89-0)

Dear Section 8(e) Coordinator:

BASF Corporation is submitting results of an OECD 421 Reproduction/Developmental Toxicity
Screening Test in Wistar Rats with Propanedioic acid, [[3,5-bis(1,1-dimethylethyl)-4-
hydroxyphenyl]methyl]butyl-, bis(1,2,2,6,6-pentamethyl-4- piperidiny) ester (CAS No. 63843-89-0),
conducted by BASF SE, Ludwigshafen, Germany. The test substance is a light stabilizer and
antioxidant in adhesives and sealants.

The aim of this study was to obtain information on the possible effects of the substance on the
integrity and performance of the male and female reproductive systems including gonadal function,
mating behavior, conception, gestation and parturition.

The study was carried out with reference to the requirements of the following guidelines:

- OECD Guidelines for Testing of Chemicals; No. 421, Reproduction/Developmental Toxicity
Screening Test (27 Jul 1995)
- EPA, Health Effects Test Guidelines; OPPTS 870.3550: Reproduction/Developmental
Toxicity Screening Test (Jul 2000)

The dose levels were 0; 0.5, 2 and 10 mg/kg body weight/day. All F0 parental animals were treated
by gavage beginning on the first day of the pre-mating period. All animals were observed daily for
any clinical signs during the study period.

After a 14-day pre-mating period, the male and female parental animals were mated overnight in a
1:1 ratio until evidence of copulation (vaginal smear). The day on which sperm was detected was
referred to as gestation day (GD) 0 and the following day as GD 1. All parental males were
sacrificed and examined after the end of the administration period (at least 28 days). The parental

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The Chemical Company

United States Environmental Protection Agency - East
June 26, 2012
Page 2

females were allowed to deliver and rear their pups until postnatal day (PND) 4. On PND 4, all pups were sacrificed and examined.

In addition, hematological examinations were performed in all animals per sex and test group towards the end of the administration period.

All F0 parental animals were sacrificed by decapitation under isoflurane anesthesia, and were assessed by gross pathology. Sex organ weights were recorded and a histopathological examination was performed for sex organs as well as liver spleen, jejunum and mesenteric lymph nodes.

The following is a summary of the most relevant results:

Test group 3: 10 mg/kg bw/d

F0 PARENTAL ANIMALS

Clinical Examinations

- Body weight loss in 4 male animals during towards the end of the administration period
- Poor general condition in 2 male animals towards the end of the administration period
- Swelling of limbs and unsteady gait in 2 male animals towards the end of the administration period
- Piloerection in 1 male animal towards the end of the administration period

Reproductive Performance

- No test substance-related, adverse findings were noted.

Clinical Pathology

- Decreased hemoglobin and hematocrit values in both sexes
- Decreased red blood cell (RBC) counts in females
- Decreased mean corpuscular volume (MCV) and mean corpuscular hemoglobin content (MCH) in males
- Increased platelet counts in females
- Increased total white blood cell (WBC) counts, absolute and relative neutrophil, absolute monocyte and absolute large unstained (LUC) counts in both sexes
- Decreased relative lymphocyte counts in both sexes



The Chemical Company

United States Environmental Protection Agency - East

June 26, 2012

Page 3

Pathology

- Minimal to moderate necrosis of the liver in 5 of 10 male animals
- Granulomatous inflammation with necrosis of the mesenteric lymph node in 9 of 10 male (graded marked to massive) and 9 of 10 female (graded moderate to marked) animals
- Granulomatous inflammation with necrosis of the spleen in 2 of 10 male (graded moderate to marked) and 2 of 10 female (graded slight to moderate) animals

F1 PUPS

Clinical Examinations/ Gross Findings

- No test substance-related, adverse findings were noted.

Test group 2: 2 mg/kg bw/d

F0 PARENTAL ANIMALS

Clinical Examinations, Reproductive Performance, Clinical Pathology and Pathology

- No test substance-related, adverse findings were noted.

F1 PUPS

Clinical Examinations/ Gross Findings

- No test substance-related, adverse findings were noted.

Test group 1: 0.5 mg/kg bw/d

F0 PARENTAL ANIMALS

Clinical Examinations, Reproductive Performance, Clinical Pathology and Pathology

- No test substance-related, adverse findings were noted.

F1 PUPS

Clinical Examinations/ Gross Findings

- No test substance-related, adverse findings were noted.



The Chemical Company

United States Environmental Protection Agency - East

June 26, 2012

Page 4

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
Janet Cerra
BASF
100 Park Avenue

Origin ID: LKKA



Florham Park, NJ 07932

Ship Date: 25JUN12
ActWgt: 10 LB
CAD: 4487533/NET3300

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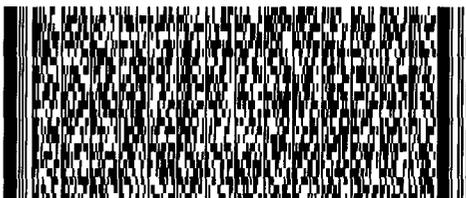
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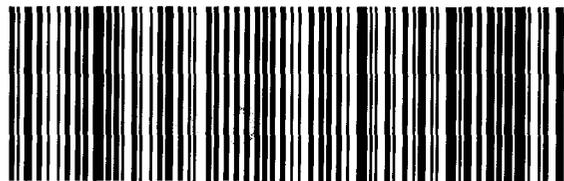
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