BASF

The Chemical Company

Helping Make Products Better™

RECEIVED
OPPT CBIC

08 JUL 28 AM 6:05

July 24, 2008

8EHQ-08-17222

Via Federal Express

United States Environmental Protection Agency - East
Attn: TSCA Section 8(e)
Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004

88080000265

Subject: Notice in Accordance with TSCA Section 8(e): Results of a Modified Developmental Toxicity Screening Study in Wistar Rats with N,N-Dimethylaminoethanol (CAS No. 108-01-0)

Dear Sir/Madam:

BASF Corporation and Taminco NV are submitting results of a pre-postnatal toxicity screening study in Wistar rats [Crl:WI(HAN)] with N,N-Dimethylaminoethanol (CAS No. 108-01-0), conducted by BASF SE, Ludwigshafen, Germany. The test substance is a high production volume chemical.

The aim of this screening was to obtain initial information on the effect of the test substance after repeated oral administration (gavage) to pregnant female Wistar rats

1) from gestation day (GD) 6 to GD 19 (prenatal study part) and

2) from GD 6 to postnatal day (PND) 3 (postnatal study part).

The pre-postnatal toxicity screening study was carried out with reference to the requirements of the following guidelines:

1. Prenatal study part:
- Corrigendum to EC Commission Directive 2004/73/EC, Part B: Methods for the determination of toxicity: Prenatal Developmental Toxicity Study; Official Journal of the European Union, No. L 216, pp. 227-235 (29 Apr 2004)
- OECD Guideline for Testing of Chemicals; Proposal for updating Guideline 414: Prenatal Developmental Toxicity Study (22 Jan 2001)
- EPA Health Effects Test Guidelines, OPPTS 870.3700: Prenatal Developmental Toxicity Study (Aug 1998)

as well as

2. Postnatal study part:
- OECD Guideline for the Testing of Chemicals; No. 421 (SIDS): Reproduction/Developmental Toxicity Screening Test (July 1995)
- EPA Health Effects Test Guidelines, OPPTS 870.3550: Reproduction/Developmental Toxicity Screening Test (July 2000)

Contains No CBI

CONTAINS NO CBI

BASF Corporation
100 Campus Drive
Florham Park, NJ 07932
Tel. (800) 526-1072
www.basf.com/usa

313114

The test substance was administered to time-mated female rats orally by gavage from GD 6 through GD 19 (prenatal study part) or GD 6 through PND 3 (postnatal study part). The dose levels were 0 (control: 10 animals), 300 (dose group 1: 10 animals) and 600 mg/kg body weight/day (dose group 2: 20 animals).

For the prenatal study part, selected dams of each group (5 animals of the control group, 5 animals of dose group 1 and 10 animals of dose group 2) were sacrificed on GD 20; dams and fetuses were examined.

For the postnatal study part, the remaining dams were allowed to litter and rear their pups until PND 4. On PND 4, all pups were sacrificed and examined grossly.

The following is a summary of the most relevant results:

Dose group 2 (600 mg/kg body weight/day):

Dams:

- Salivation after treatment (20 out of 20 animals)
- Respiratory sounds (7 out of 20 animals)
- Statistically significantly reduced mean food consumption compared to the control group (set to 100%), i.e. between GD 6-8 (81%) and GD 8-10 (78%)
- Statistically significantly reduced mean body weight compared to the control group (set to 100%), i.e. on GD 13 (93%)
- Statistically significantly reduced mean body weight change compared to the control group (set to 100%), i.e. between GD 8-10 (52%)
- One animal sacrificed moribund on GD 14 (gross pathological examination revealed stomach erosions and no feces in intestine)
- One animal found dead on GD 20 (gross pathological examination revealed stomach ulcerations)

Prenatal study part (10 dams sacrificed on GD 20):

Dams:

- Increased post-implantation loss compared to the control group and the historical control data (11.8% vs. 5.2% in control)
- Stomach erosions/ulcera (8 out of 10 animals)
- Statistically significantly increased mean liver weight (118%) compared to the control group (set to 100%)

Fetuses:

- No test substance-related findings

Postnatal study part (8 dams):

Dams:
- Stomach erosions/ulcera (8 out of 8 animals)
- One out of 8 animals did not deliver (7 animals left for further assessment)
- Salivation after treatment (7 out of 7 animals)
- Statistically significantly reduced mean food consumption (81% between PND 0-4) compared to the control group (set to 100%)
- Live birth index of 91% (control: 100%)

Pups:
- Six stillborn pups in 7 litters (64 pups *in toto*, 58 liveborn)
- Twenty-four pups out of 58 died ahead of schedule
- Nine pups out of 58 were cannibalized
- No more pups alive in 4 out of 7 litters (2 litters on PND 1, 1 on PND 2, 1 on PND 3)
- Viability index of 43% (control: 100%)
- Statistically significantly reduced mean body weight compared to the control group (set to 100%), i.e. on PND 1 (76%) and on PND 4 (71%)
- Statistically significantly reduced mean body weight change (57% between PND 1-4) compared to the control group (set to 100%)
- Twelve runts (no runt in the control)

Dose group 1 (300 mg/kg body weight/day):

Dams:
- Salivation after treatment (10 out of 10 animals)

Prenatal study part (5 dams):

Dams:
- Stomach erosions/ulcera (4 out of 5 animals)
- Increased post-implantation loss compared to the control group and the historical control data (15.2% vs. 5.2% in control)
- Increased resorptions (mean/litter) compared to the control group and the historical control data (1.4% vs. 0.6% in control)

Fetuses:
- No test substance-related findings

Postnatal study part (5 dams):

Dams:
- Stomach erosions/ulcera (5 out of 5 animals)
- Salivation after treatment (5 out of 5 animals)

Pups:
- No test substance-related findings

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 call Janet Cerra at (973) 245-6693.

Sincerely,

Janet Cerra

Janet Cerra
Product Regulatory Center of Expertise
North America

/jc

881st Letter.doc

BASF Corporation
100 Campus Drive
Florham Park, NJ 07932
Tel. (800) 526-1072
www.basf.com/usa

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

Florham Park, NJ 07932

JCLS060408/20/23

Ship Date: 24JUL08
ActWgt: 1.0 LB
System#: 4487533/INET8061
Account#: S *********

Delivery Address Bar Code

Ref # 673230
Invoice #
PO #
Dept #

SHIP TO: (202) 564-8930 **BILL SENDER**

Attn: TSCA Section 8e
USEPA East
Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004

TRK# 0201 7970 3337 1336

FRI - 25JUL **A1**
STANDARD OVERNIGHT

ZD RDVA

20004
DC-US
IAD

After printing this label:
1. Use the 'Print' button on this page to print your label to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

Warning: Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges, along with the cancellation of your FedEx account number.

Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com.FedEx will not be responsible for any claim in excess of $100 per package, whether the result of loss, damage, delay, non-delivery,misdelivery,or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim.Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic valueof the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental,consequential, or special is limited to the greater of $100 or the authorized declared value Recovery cannot exceed actual documented loss.Maximum for items of extraordinary value is $500, e.g. jewelry, precious metals, negotiable instruments and other items listed in our ServiceGuide. Written claims must be filed within strict time limits, see current FedEx Service Guide.