

ORIGINAL

**TSCA NON-CONFIDENTIAL BUSINESS INFORMATION**

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8FHQ-10-17948	8810000277	5/19/10

COMMENTS:

**DOES NOT CONTAIN CBI**



The Chemical Company

326996

RECEIVED  
OPPT COIC

Helping Make  
Products Better™

10 MAY 19 AM 6:01

May 17, 2010



8EHQ-0510-17948A

DCN: 88100000277

**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): Preliminary Results of a Combined Repeated-Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test in Wistar Rats with Alkenyl Succinic Anhydride (CAS No. 68784-12-3)

Dear Sir/Madam:

BASF Corporation is submitting, on behalf of Consortium members<sup>1</sup>, preliminary results of a Combined Repeated-Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test in Wistar rats [CrI:WI(HAN)] with Alkenyl Succinic Anhydride (CAS No. 68784-12-3), conducted by BASF SE, Ludwigshafen, Germany. The substance is used as a sizing agent for paper.

The aim of this study was to obtain information on the possible effects of Alkenyl Succinic Anhydride (ASA) 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. 422, Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (22 Mar 1996)
- EPA, Health Effects Test Guidelines; OPPTS 870.3650: Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (Jul 2000)

The dose levels were 0; 100, 300 and 1000 mg/kg body weight/day (gavage). 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 surviving parental males

<sup>1</sup> Consortium members include: Hercules BV, an Ashland Affiliate, Pentagon Chemical Specialties Limited, Eka Chemicals AB, Bercen, Inc., Dixie Chemical Company, Inc., Kemira Chemie GmbH, Mare S.p.A.



The Chemical Company

United States Environmental Protection Agency – East

May 17, 2010

Page 2

---

were sacrificed and examined after the end of the administration period (at least 28 days). The parental females were allowed to deliver and rear their pups until postnatal day (PND) 4. On PND 4, all pups were sacrificed and examined. Towards the end of the administration period a functional observation battery (FOB) was performed and motor activity was recorded.

The notification presents a summary of the most important findings of the study. The post-mortal part of the study is still ongoing, and a final report including interpretation of the results (e.g. cause of increased pup mortality) will be available by the end of June 2010.

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

Test group 3 (1000 mg/kg body weight/day):

*Males:*

- Salivation after treatment in up to 8 of 10 animals

*Dams:*

- Salivation after treatment in up to 3 of 10 animals
- Piloerection in up to 4 of 10 animals during lactation
- Poor general state in 2 of 10 animals during lactation
- Insufficient maternal care in 5 of 9 animals during lactation
- Increased pup mortality, i.e. 30% during lactation period (dead or cannibalized)
- 2 dams with complete litter loss

Test group 2 (300 mg/kg body weight/day):

*Males:*

- Salivation after treatment in up to 3 of 10 animals

*Dams:*

- Salivation after treatment in up to 2 of 10 animals
- Piloerection in up to 1 of 10 animals during lactation
- Insufficient maternal care in 1 of 10 animals during lactation
- Increased pup mortality, i.e. 17% during lactation period (dead or cannibalized)
- 1 dam with complete litter loss



The Chemical Company

United States Environmental Protection Agency – East  
May 17, 2010  
Page 3

---

Test group 1 (100 mg/kg body weight/day):

*Males:*

- No treatment-related findings were observed.

*Dams:*

- Poor general state in 1 of 10 animals during lactation
- Piloerection in up to 1 of 10 animals during lactation
- Insufficient maternal care in 1 of 10 animals during lactation
- Increased pup mortality, i.e. 10% during lactation period (dead or cannibalized)
- 1 dam with complete litter loss

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

1061st Letter.doc

From: Origin ID: LKKA (973) 245-6693  
Janet Cerra  
BASF  
100 Campus Drive  
  
Florham Park, NJ 07932



J10101002220224

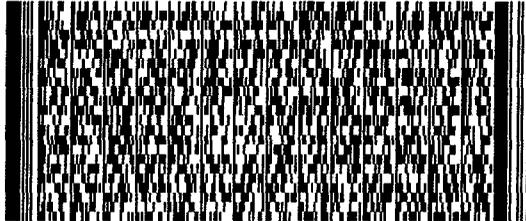
Ship Date: 17MAY10  
ActWgt: 1.0 LB  
CAD: 4487533/INET3010

Delivery Address Bar Code



Ref # US635018  
Invoice #  
PO #  
Dept #

SHIP TO: (202) 564-8930 BILL SENDER  
**Attn: TSCA Section 8(e)**  
**USEPA East**  
**Room 6428**  
**1201 Constitution Avenue, NW**  
**Washington, DC 20004**



TRK# 7986 6875 4331  
0201

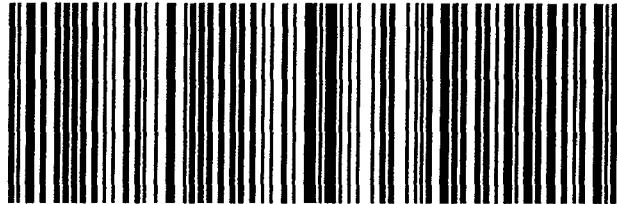
TUE - 18 MAY A1  
STANDARD OVERNIG

20004

DC-US

DCA

ZD RDVA



605G1/168/5FE8

**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 can 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 value of the package, loss of sales, income interest, profit, attorney's 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 Service Guide. Written claims must be filed within strict time limits, see current FedEx Service Guide.

Global Home | Small Business Center | Service Info | About FedEx | Investor Relations | Careers | fedex.com Terms of Use | Security & Privacy | Site  
This site is protected by copyright and trademark laws under US and International law. All rights reserved. © 1995- 2010 FedEx