

4/11/08

N C I C,

Per request of Submitted
The status of BEHP-08-17117,
DLP: 48080000160 has been
changed from "CBI" to "Non-CBI".

Please replace your sanitized
copy with this document.

The "company sanitized" copy was
originally placed in ^{the} March 2008 folder.
The document was deleted, ^{from that folder} and the
"NCBI" version was placed in the
April 2008 folder. The sanitized and
NCBI versions were returned to the

CBIC.

4/15/08
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The Chemical Company

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April 7, 2008

Via Federal Express

Contains No CBI

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 Screening Study in Beagle Dogs with 2-Methyl-3(4-tert-butylphenyl)-propanal, 4-(1,1-Dimethylethyl)-, alpha.-methylbenzenepropanal (CAS No. 80-54-6)

Dear Sir/Madam:

BASF Corporation is submitting results of a repeated dose oral toxicity study in dogs with 2-Methyl-3(4-tert-butylphenyl)-propanal, 4-(1,1-Dimethylethyl)-, alpha.-methylbenzenepropanal (CAS No. 80-54-6), conducted by BASF SE, Ludwigshafen, Germany. The test substance is a fragrance.

The substance was administered to groups of 10 male purebred Beagle dogs via gelatin capsules at concentrations of 0 and 200 mg/kg body weight/day for 2 weeks.

The following findings were observed:

Clinical Pathology:

Changes indicating anemia and liver toxicity were observed.

Pathology:

Decreased absolute and relative testes and prostate weights, increased liver weights were observed.

Histopathology:

A slight to severe degeneration of seminiferous tubules in 9/10 treated males was observed. 3/10 treated males exhibited a multifocal atrophy of the prostate. In the liver, a slight centrilobular hypertrophy of hepatocytes was noted for all treated males.



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United States Environmental Protection Agency - East

April 7, 2008

Page 2

Andrological and spermatological examinations:

Marked changes in semen quality:

- marked decrease in the percentage of progressively motile spermatozoa
- marked increase of spermatozoa with damaged plasma membrane and with neck- and mid-piece anomalies

Specification of sperm neck- and mid-piece anomalies before and after treatment in ejaculates of the 200 mg/kg dosed dogs showing an increased total percentage of morphologically altered spermatozoa after treatment.

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

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