

ORIGINAL

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DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ - 09-17719	89110000304	5/4/11

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MR# 335 138



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11 MAY -4 AM 10: 28

April 29, 2011

**Via Federal Express**

Attention: TSCA Declassification Coordinator

United States Environmental Protection Agency  
Office of Pollution Prevention and Toxics  
Confidential Business Information Center (CBIC)  
EPA East Building, Room 6428  
1201 Constitution Avenue  
Washington, DC 20004



**Subject: Declassification Activity, Health and Safety Filing  
DCN: 8EHQ-09-17719**

Dear TSCA Declassification Coordinator:

In response to Mr. Sherlock's electronic mail request of March 16, 2011 regarding confidentiality claims for the identity of the chemical substance that was reported under TSCA Section 8(e) dated November 12, 2009, BASF Corporation hereby withdraws all claims of confidentiality made with respect to the Section 8(e) report in question.

Please note that this withdrawal of confidentiality is intended only to allow EPA to reveal to the public the information that was claimed confidential at the time of the report in question. BASF Corporation is not relinquishing any property rights in the study in question.

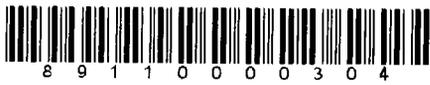
Attached is a public version of the document (copy of the original submission), with the declassified data circled and document control number (DCN) identified.

If you have any questions regarding this letter, please contact Janet Cerra at (973) 245-6693.

Sincerely,  
*Janet Cerra*  
Janet Cerra

/

Enclosure



1026th\_CBI DeclassLetter.doc

BASF Corporation  
100 Campus Drive  
Florham Park, NJ 07932  
Tel (800) 526-1072  
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November 12, 2009

**Declassification Activity, Health and Safety Filing**  
**DCN: 8EHQ-09-17719**

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 Combined Repeated Dose Toxicity Study in Wistar Rats with Polyetherpolyol (CAS No. 29860-47-7)

Dear Sir/Madam:

BASF Corporation is submitting results of a Combined Repeated Dose Toxicity Study with the reproduction/developmental toxicity screening test in Wistar rats, according to OECD Guideline 421, with Polyetherpolyol (CAS No. 29860-47-7). The study was conducted by BASF SE, Ludwigshafen, Germany. The test substance is a constituent of polyurethane, industrial handling.

The test substance preparation was oral administered to groups of 10 male as well as 10 female animals at dose levels of 1000, 300 and 100 mg/kg body weight/day by gavage. Male and female rats were dosed for 14 days as a pre-mating period, followed by 14 days administration during mating. Thereafter, parental males were sacrificed and examined according to the test guideline OECD 421. The parental females were allowed to deliver and to rear their pups up to day 4 post partum (p.p.) and were sacrificed and examined thereafter. Additionally, on day 4 p.p., all pups were sacrificed and examined according to the above-mentioned test guideline.

The sperm parameters revealed statistically significant reduced total spermatids per g testis compared to the corresponding controls, as the following table demonstrate:

Dose level (mg/kg body weight/day)	0	100	300	1000
Mean total spermatids/ g testis	106	110	109	88*

\* :  $p \leq 0.05$ , Wilcoxon-test with Bonferoni-Holm adjustment (one-sided)

United States Environmental Protection Agency - East

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The historical control data for sperm evaluation in our laboratory is shown in the following table.  
Total spermatids/ g testis, historical control data:

<b>Nos. of animals examined</b>	<b>Overall mean</b>	<b>Range of study means, minimum</b>	<b>Range of study means, maximum</b>
676	119	94	144

Thus, the above mentioned significantly reduced total spermatids per g testis in high dosed males (1000 mg/kg body weight per day) are just outside of the historical range.

A lower value of delivered pups per dam was noted in high dose females (1000 mg/kg body weight per day) as the following table demonstrates:

<b>Dose level (mg/kg body weight/day)</b>	<b>0</b>	<b>100</b>	<b>300</b>	<b>1000</b>
Mean pups delivered per dam	14.1	13.4	13.1	10.6*

\* :  $p \leq 0.05$ , Dunnett-test (two-sided)

The historical control data for that parameter is shown in the following table:

<b>Nos. of studies</b>	<b>Overall mean</b>	<b>Range of study means, minimum</b>	<b>Range of study means, maximum</b>
14	10.6	9.3	11.7

Thus, the above-mentioned significantly lower value of delivered pups per dam compared to controls is within the historical control data range. Moreover, the control value was beyond the historical control data range, which explains the statistical significance of the mean pups delivered per dam in high dose females.

In conclusion, two marginal effects were noted which were either within or just below the historical range. No findings were noted in histopathological evaluation of the testis at any dose level. At this stage of the investigation, it is not possible to draw definitive conclusions concerning the association of these effects with the administration of the test substance.



The Chemical Company

Declassification Activity, Health and Safety Filing  
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BASF Corporation understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note that a sanitized version of this letter is enclosed, treating the chemical identities as confidential business information.

The information considered confidential is highlighted, in accordance with U.S. EPA policy. The non-confidential name can be referred to as 1,1,1-Trimethylolpropane, Exthoxylated.

A confidentiality substantiation questionnaire is being submitted for this substance.

Please send all correspondence related to this submission to the attention of Janet Cerra. If you have any questions, please call (973) 245-6693.

Sincerely,

*Janet Cerra*

Janet Cerra

Enclosure

1026th Confidnt'l Letter.doc

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

Origin ID: LKKA

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Express



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Florham Park, NJ 07932

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**TSCA Declassification Coordinator**  
**USEPA**  
EPA East Building, Rm. 6428 (CBIC)  
1201 Constitution Ave.  
Washington, DC 20004

Ref # US635018  
Invoice #  
PO #  
Dept #

**TUE - 03 MAY A1**  
**STANDARD OVERNIGHT**

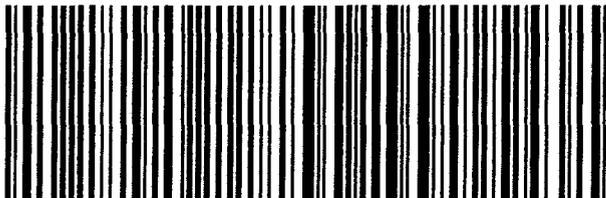
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