



September 11, 2009

Via Overnight Courier

Document Processing Center (Mail Code 7404M)  
EPA East - Room 6428  
Attention: TSCA 8(e) Coordinator  
U.S. Environmental Protection Agency  
1201 Constitution Ave., NW  
Washington, DC 20004



09 SEP 14 AM 11:58  
RECEIVED  
OFFICE

RE: **Undeliverable Certified Mail – TSCA 8(e) - Preliminary data – Two Generation  
Reproduction Study (OECD Guideline 416) using the dihydrochloride salt of XTJ-588  
(monoethyleneglycol polybutyleneoxide diamine)**

Dear TSCA 8(e) Coordinator,

On July 30, 2009, Huntsman Petrochemicals Corporation (Huntsman) sent a letter to EPA, pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA), regarding preliminary findings on the above study. This notification was sent to EPA within two days of receipt of this information from our contract testing laboratory via USPS Certified Mail with return receipt. The return receipt was postmarked on September 1, 2009, and was received by Huntsman shortly thereafter. On September 4<sup>th</sup>, the actual envelope containing the original TSCA 8(e) notification was received by Huntsman, unopened, and stamped "Returned to Sender." All of the certified mail document labels were blackened and mostly illegible. In addition, the original TSCA 8(e) letter had deteriorated to the point of being fragile. The certified mail Article Number identification label on the original TSCA 8(e) letter was also blackened, similar to the other labels. I'm not certain as to what may have happened to these documents, but I believe that the documents did not fare well during the routine screening process for mail sent to US Government facilities.

I've included the original documents for your inspection, along with a copy of the original TSCA 8(e) letter. To prevent any further delay in getting this information to EPA, these documents have been sent via overnight courier to the appropriate address. Please note that the original document was sent to EPA within the specified time frame for TSCA 8(e) submissions.

As stated in our original TSCA 8(e) letter to EPA, Huntsman will provide to EPA any additional findings from this study that may be required pursuant to TSCA Section 8(e) reporting requirements. Upon conclusion of this study, Huntsman will provide to EPA a copy of the final report from this study.

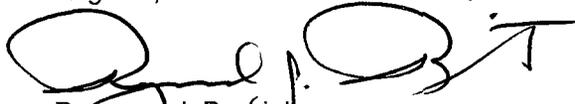
**Contains No CBI**

**CONTAINS NO CBI**

MR 321564

As always, if I can provide any additional information on this study or the preliminary findings reported above, please call me at (281) 719-3017, or contact me via e-mail at: [Ray\\_Papciak@huntsman.com](mailto:Ray_Papciak@huntsman.com).

Regards,

A handwritten signature in black ink, appearing to read 'Ray J. Papciak', with a stylized flourish at the end.

Raymond J. Papciak  
Manager, Product Safety



# **HUNTSMAN**

Enriching lives through innovation

July 30, 2009

By Certified Mail

TSCA Confidential Business Information Center (7407M)  
EPA East – Room 6428  
Office of Pollution Prevention and Toxics  
US EPA  
1200 Pennsylvania Ave, NW  
Washington, DC 20460-0001

**Attention: TSCA 8(e)**

**RE: Preliminary data – Two Generation Reproduction Study (OECD Guideline 416) using the dihydrochloride salt of XTJ-568 (monoethyleneglycol polybutyleneoxide diamine)**

On July 28, 2009, Huntsman Petrochemicals Corporation (Huntsman) received preliminary and unaudited data from a contract toxicity testing laboratory, NOTOX B.V., from a two generation reproduction toxicity study using the dihydrochloride salt of an experimental Huntsman product, XTJ-568 (monoethyleneglycol polybutyleneoxide diamine). Huntsman is submitting a summary of this information pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA). Huntsman has not made a determination as to whether a significant risk of injury to human health or the environment is actually presented by these findings.

These preliminary findings are from a two generation reproduction toxicity study in rats using XTJ-568 dihydrochloride salt dosed by gavage, conducted according to OECD Guideline 416. This study, currently underway, is being conducted in support of the European Union (EU) new product notification process for XTJ-568. After pre-study discussions with the EU authorities, approval was obtained to use the neutralized dihydrochloride salt of XTJ-568 for gavage studies, due to the known corrosive properties of XTJ-568. On the basis of a rangefinding study, doses selected for this study were 0, 171, 513 or 1140 mg/kg/day (Study Groups 1 through 4, respectively).

The preliminary findings are as follows:

- The mean number of the F<sub>1</sub> generation live pups at first litter check is 11.1, 11.4, 11.6 and 7.9 for Groups 1, 2, 3 and 4, respectively. Mean pup weight and individual pup data (clinical signs) are comparable (unaffected) for all groups. The decrement of 3.2 pups per litter in the high dose group (Group 4) as compared to the control group is statistically significant and outside the range of the laboratory's historical control data.
- Examination of the reproductive organs of the F<sub>0</sub> generation males indicated the following statistically significant effects:
  - Decreased sperm motility (Groups 2, 3, 4 versus Group 1);
  - Increased numbers of abnormal sperm (Group 4 versus Group 1);
  - Decreased sperm cell count, sperm concentration, and sperm production rate in the testis (Group 4 versus Group 1);
  - Decreased epididymides weight (Group 4 versus Group 1); and
  - Decreased sperm cell count and sperm concentration in the epididymides (Group 4 versus Group 1).

Based on these preliminary findings, we believe that there is a treatment-related effect on male reproduction in the F<sub>0</sub> generation.

As a follow-up to these findings, Huntsman has requested that NOTOX conduct sperm counts and sperm morphology evaluations for the intermediate dose groups (Groups 2 and 3) of the F<sub>0</sub> generation to determine a no-observed-adverse-effect level (NOAEL) for reproduction.

Huntsman will provide to EPA any additional findings from this study that may be required pursuant to TSCA Section 8(e) reporting requirements. Upon conclusion of this study, Huntsman will provide to EPA a copy of the final report from this study.

As always, if I can provide any additional information on this study or the preliminary findings reported above, please call me at (281) 719-3017, or contact me via e-mail at: [Ray\\_Papciak@huntsman.com](mailto:Ray_Papciak@huntsman.com).

Regards,

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Raymond J. Papciak  
Manager, Product Safety