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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-07-16826**

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 May 8, 2007, 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

761st_CBI DeclassLetter.doc



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

CONTAINS NO CBI



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May 8, 2007

Declassification Activity, Health and Safety Filing
DCN: 8EHQ-07-16826

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 Prenatal Developmental Screening Study in Rats with N-Methylvalerolactam (CAS No. 931-20-4)

Dear Sir/Madam:

BASF Corporation is submitting results of a Prenatal Developmental Screening Study in Wistar Rats (strain Crl:WI(Han)) with N-Methylvalerolactam (CAS No. 931-20-4) conducted by BASF Aktiengesellschaft, Ludwigshafen, Germany. The test substance is a developmental solvent.

Scope of examinations:

The study was carried out with reference to the requirements of international guidelines such as:

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

The test substance was administered by gavage to 10 pregnant female rats/group at doses of 0, 100, 300 and 1000 mg/kg body weight on day 6 through day 19 post coitum. The fetuses were assessed for external, soft tissue and/or skeletal (incl. cartilage) findings.

The following is a summary of the most relevant results:

The exposure to 1000 mg/kg bw/day caused excessive signs of maternal toxicity, such as markedly reduced food consumption and body weight gain. At caesarean section, the carcass weight of these dams was 16% below control and the corrected body weight gain over the treatment period was 94% below control. The maternal toxicity caused the intrauterine death of all offspring. Thus, this dose level is considered too high and should not be taken into account for the assessment of potential prenatal developmental toxicity of the test compound.



The Chemical Company

Declassification Activity, Health and Safety Filing
DCN: 8EHQ-07-16826

United States Environmental Protection Agency – East
May 8, 2007
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Maternal toxicity was still marked at the At 300 mg/kg bw/day level, and moderate at the 100 mg/kg bw/day level. At caesarean section, the carcass weight of the 300 mg/kg bw/day dams was 18% below control and the corrected body weight gain over the treatment period was 79% below control, whereas the carcass weight of the 100 mg/kg bw/day dams was 10% below control and the corrected body weight gain over the treatment period was 40% below control.

At 300 mg/kg bw/day a marginally increased rate of intrauterine deaths (17.5% of implants died) lead to a marginally lower average litter size (83% of control), though not statistically significant. Placental and fetal weights were significantly decreased (-31% and -33%, respectively) at this dose level.

In the 300 mg/kg bw/day dose group 5/80 (6.3%) fetuses from 4/10 (40%) litters had malformations, such as mandibular micrognathia (2), aglossia (2), cleft palate (2), one fetus having a combination of all these findings. These malformations were accompanied by an increased incidence of skeletal variations, consisting mainly of delays or disturbances of ossification in a variety of skeletal structures.

No significant effects on implants and placental/fetal weights were noted at 100 mg/kg bw/day. No effects on prenatal development were noted at 100 mg/kg bw/day.

Although the findings are not considered to indicate a substantial risk to human health or the environment, 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 is referred to as "Substituted Nitrogen Containing Heterocycle."

A confidentiality substantiation questionnaire is being submitted for the substance.

Please send all correspondence related to the TSCA 8(e) submissions to the attention of Janet Cerra. If you have any questions, please call (973) 245-6693.

Sincerely,

Janet Cerra

Janet Cerra
Product Regulatory Center of Expertise

Enclosures
761st Confidnt'l Letter.doc

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From: (973) 245-6693
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Origin ID: LKKA



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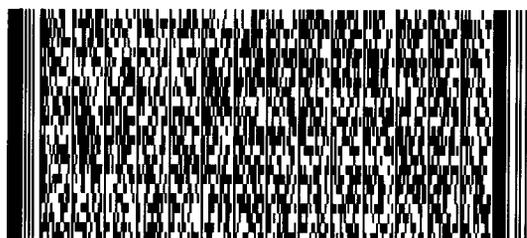


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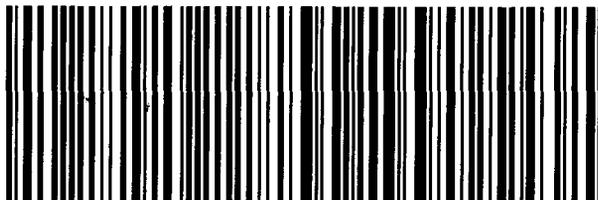
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