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February 27, 2008

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 TSCA Section 8(e): Interim Results of an Extended 1-
Generation Reproduction Toxicity Range-Finding Study in Wistar Rats with
Lysmeral - TP (CAS No. 80-54-6)

Dear Sir/Madam:

BASF Corporation and Innospec Active Chemicals are submitting results of a 1-generation reproduction toxicity range-finding study in Wistar rats [Cri:WI(HAN)], conducted by BASF SE, Ludwigshafen, Germany. The test substance Lysmeral - TP (CAS No. 80-54-6) is a powder formulation containing 30% Lysmeral. The substance is a fragrance.

The study was carried out with reference to the requirements of the following guidelines:

- Corrigendum to EC Commission Directive 2004/73/EC, Part B (29 Apr 2004): Methods for the determination of toxicity: Two-Generation Reproduction Toxicity Study; Official Journal of the European Union, No. L 216, pp. 236-246 (2004)
- EPA Health Effects Test Guidelines, OPPTS 870.3800: Reproduction and Fertility Effects (Aug 1998)
- OECD Guideline for Testing of Chemicals; Proposal for updating Guideline 416: Two-Generation Reproduction Toxicity Study (22 Jan 2001)

The test substance was administered to groups of 10 male and 10 female young Wistar rats (F0 parental generation) via the diet. The concentrations of the compound in the diet were 400; 800; 1,700 and 3,400 ppm, during lactation the dams were fed 200; 400; 850 and 1,700 ppm. About 6 weeks after the beginning of treatment, F0 animals were mated to produce a litter (F1). Mating pairs were from the same dose group. The female F0 animals were allowed to deliver and rear their F1 pups until weaning (postnatal day 21). The inlife part of the study was terminated with the sacrifice of the F0 and F1 animals after weaning of F1. All sacrificed animals were assessed by gross pathology. Additionally, clinical-pathological examinations were conducted in the F0 and F1 animals, and sperm evaluation as well as histopathology of sexual organs was performed in the F0 males.

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The following is a summary of the most relevant results:

Signs of general systemic toxicity were noted in the 800, 1700 and 3400 ppm F0 parental animals, such as reduced feed consumption and body weights/body weight gain. F0 parental animals showed also slight changes of some blood chemistry parameters (decreased serum choline esterase, increased gamma-GT, ALAT, GLDH, ALP) at 400 ppm and above.

Lysmeral had adverse effects on mating and fertility indices at dose levels of 1,700 and 3,400 ppm. In these groups only 50 or 80%, respectively, of the pairing pairs showed signs of copulation, none of them was able to generate F1-offspring. Animals of the 400 and 800 ppm groups normally mated and generated offspring. The offspring of these groups had a lower body weight at birth and their body weight remained lower until weaning.

F0 males at 1,700 and 3,400 ppm had a reduced size and weight of testes and epididymides. These males also showed markedly decreased sperm and spermatid numbers as well as a marked decrease of the percentage of motile sperm. Histopathology revealed a diffuse testicular degeneration and epididymal aspermia.

The findings reported here are consistent with earlier data reported by Givaudan; however, in the current study the test substance was administered as a dietary admixture, while the Givaudan study was performed by gavage. Consequently, the information reported here may not necessarily be considered as new information. Nevertheless, it was considered prudent to report this information under TSCA section 8(e).

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

Sincerely,

Janet Cerra

Janet Cerra
Product Regulatory Center of Excellence

/

cc: Innospec Active Chemicals
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