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January 4, 2011

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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 One Generation Rangefinding and a Subsequent Two Generation Reproduction Toxicity Study in Wistar Rats with [redacted]

Dear Sir/Madam:

[[redacted]] is submitting results of a One Generation Rangefinding and a Subsequent Two Generation Reproduction Toxicity Study in Wistar Rats [BrlHan:Wist@Jcl(GALAS)], administration via diet, according to OECD Guideline 416, with [redacted], conducted by Safety Research Institute for Chemical Compounds Co., Ltd., Sapporo, Japan on behalf of [[redacted]] and [[redacted]]. The test substance is an experimental pesticide.

In the One Generation study, the test substance was administered to groups of 8 male and 8 female young Wistar rats (F0 parental generation) via the diet. The concentration levels were 0, 150, 1500, 3000 and 6000 ppm. About 3 weeks after the beginning of treatment, F0 animals were mated to produce a litter (F1). Mating pairs were from the same dose group. Pregnant females were allowed to give birth and the offspring was brought up until postnatal day (PND) 21. The study was terminated with the sacrifice of the F1 weanlings and F0 adult animals.

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In the Two Generation study, the test substance was administered to groups of 25 male and 25 female young Wistar rats (F0 parental generation) via the diet. The concentrations of the compound in the diet were 0; 100, 300 and 1000 ppm. About 10 weeks after the beginning of treatment, F0 animals were mated to produce a litter (F1). Mating pairs were from the same dose group. Groups of 25 males and 25 females selected from F1 pups as F1 parental generation were exposed to the same doses post weaning, and after 10 weeks the breeding program was repeated to produce F2 litter. The study was terminated with the sacrifice of the F2 weanlings and F1 adult animals.

Taking both studies together, food consumption was reduced during lactation at dose levels of 1500 ppm and above, and body weight gain was reduced during late gestation and lactation at dose levels of 3000 ppm and above. Estrous cycle length was increased at doses of 3000 ppm and above as was gestation length at 6000 ppm only. Organ weight increases were noted for liver (beginning at 100 ppm), adrenals (beginning at 1000 ppm), spleen (beginning at 1000 ppm) and thymus (beginning at 3000 ppm). Organ weights were decreased for pituitary and uterus (beginning at 1000 ppm) as well as epididymis, seminal vesicle and prostate (beginning at 3000 ppm).

Fertility was unaffected in all dose groups. Pregnancy was unaffected up to 1500 ppm. Number of implants and litter size were decreased at 3000 and 6000 ppm.

Pup mortality on postnatal days 1-4 was increased at all dose levels and, for the Two Generation study, in both generations. An overview is given in Table 1:

Table 1

Dose / Observation	Control	100 ppm	150 ppm	300 ppm	1000 ppm	1500 ppm	3000 ppm	6000 ppm
F1								
Dead/cannibalized pups PND 1-4 (%)	3.71 (11/296)	7.01 (19/271)	5.54 (5/90)	5.49 (16/291)	8.72 (25/287)	16.75 (16/84)	53.49 (43/72)	100 (34/34)
Affected Litters	5	6		9	11			
F2								
Dead/cannibalized pups PND 1-4 (%)	3.69 (11/278)	5.95 (16/269)		9.63 (26/270)	10.58 (29/274)			
AffectedLitters	6	7		9	8			

Necropsy of pups did not reveal adverse findings. After PND 4, postnatal survival and growth of offspring was not affected.

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[[redacted]] understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note that a confidential version of this letter is enclosed, treating the chemical identity and company identity as Confidential Business Information.

A Confidentiality Substantiation Questionnaire is being submitted for the substances.

Sincerely,

Enclosures

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