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TSCA Document Processing Center
U.S. Environmental Protection Agency
Office of Pollution Prevention & Toxics
Mail Code 7407M
EPA East Building, Room 6428
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

COMPANY SANITIZED

Attn: TSCA §8(e) Submittal

Re: TSCA §8(e) Submittal for

is submitting this notice pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA). The submittal is for

This material has been tested under the name SP 7077.

A two-generation rat reproductive toxicity study was conducted according to U.S. EPA and OECD testing guideline specifications. Male and female rats (F₀ generation) were administered SP 7077 by daily gavage at dose levels of 0 (corn oil vehicle), 5, 30, and 150 mg/kg/day for ten weeks prior to estrus evaluation, mating, and throughout the mating, gestation, and lactation periods. The offspring, identified as the F₁, were evaluated for litter size and viability, birth weight, anogenital distance, growth during lactation, and clinical observations. Selected F₁ offspring from each litter were evaluated for sexual maturation and received the test material by oral gavage for a minimum of ten weeks prior to mating, gestation, and lactation for similar evaluation. All animals on the study were terminated at the end of the F₂ weaning period.

The attached table contains data from the study. For the F₁ females in the 150 mg/kg/day group, sexual maturation occurred at an earlier age and at a lighter body weight than in the control group; these differences were statistically significant. Sexual maturation in F₁ males appeared to be slightly delayed but neither age nor weight were statistically different from the control value. These results were unknown at the time of F₂ weaning (the laboratory collected all data manually and did not analyze the data until the in-life phase was complete) and thus the F₂ offspring were not evaluated for this parameter. There were no

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differences amongst F₁ or F₂ pups for anogenital distance. Reproductive parameters were unaffected in both generations.

In F₀ and F₁ males, the weight of the seminal vesicle with coagulating gland (SVCG) was statistically significantly reduced at 30 and 150 mg/kg/day (F₀ males) and at all dose levels (F₁ males). The weight of the SVCG relative to body weight was statistically reduced at all exposure levels in the F₀ males and at 30 and 150 mg/kg/day in the F₁ males. This finding was reported pursuant to Section 8(e) of TSCA in 1998 based upon data from 28-day and 90-day repeated-dose oral toxicity studies. The current submission reports this finding at lower exposure levels. In the current study, no microscopic changes related to exposure were found in these organs; the prior submission reported reduced colloid in the seminal vesicles and prostate at 600 mg/kg/day.

All data are currently in unaudited draft form and we have not received an interpretation of the results. When the final report is completed, it will be submitted to you.

We consider this letter to be "Confidential Business Information" (CBI); therefore, we are also enclosing a "sanitized" (non-CBI) version.

If you have any questions, please contact me at
phone at

or by

Sincerely

Attachment (1)

**Unaudited Data from 703/256: Two-Generation Rat Reproduction Study
with SP 7077**

Parameter	SP 7077 in corn oil (mg/kg/day)			
	0	5	50	150
Sexual Maturation:				
Vaginal Opening (days) - F ₁	34.17 ± 2.89	34.21 ± 1.86	34.52 ± 1.38	31.57** ± 1.81
Body Weight at Maturation (g)	106.76 ± 11.20	107.93 ± 11.35	108.52 ± 9.99	92.43*** ± 11.74
Preputial Separation (days) - F ₁	43.75 ± 1.76	43.34 ± 2.00	44.38 ± 1.90	44.72 ± 1.94
Body Weight at Maturation (g)	199.82 ± 18.21	199.10 ± 26.88	209.97 ± 22.31	214.48 ± 25.36
Organ Weight				
Seminal Vesicle/ Coagulating Gland (g):				
F ₀	2.726 ± 0.384	2.498 ± 0.370	2.480* ± 0.345	2.335*** ± 0.381
F ₁	2.758 ± 0.501	2.434* ± 0.378	2.371** ± 0.313	2.261*** ± 0.397
SV/CG- Relative to Body Weight:				
F ₀	0.435 ± 0.062	0.394* ± 0.062	0.401* ± 0.056	0.384* ± 0.083
F ₁	0.0447 ± 0.070	0.416 ± 0.060	0.398* ± 0.055	0.392* ± 0.061
Ano-genital Distance (mm):				
Males - F ₀	2.63 ± 0.22	2.61 ± 0.19	2.55 ± 0.26	2.59 ± 0.24
Males - F ₁	2.57 ± 0.13	2.54 ± 0.15	2.52 ± 0.14	2.48 ± 0.26
Females - F ₀	1.12 ± 0.12	1.10 ± 0.14	1.01 ± 0.14	1.08 ± 0.13
Females - F ₁	1.06 ± 0.05	1.05 ± 0.05	1.08 ± 0.06	1.11 ± 0.26

* p < 0.05; ** p < 0.01; *** p < 0.001