

ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ-10-17920	89100000298	8/4/10

COMMENTS:

DOES NOT CONTAIN CBI

MR#328968



DuPont Haskell Global Centers
for Health and Environmental Sciences
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Attention: 8(e) Coordinator
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U.S. Environmental Protection Agency, ICC Building
1201 Constitution Ave., NW
Washington, DC 20004

**Public Copy
No CBI**

8EHQ-0810-17920B
DCN:89100000298

Dear 8(e) Coordinator:



8EHQ-10-17920
o-Phenylenediamine (CAS # 95-54-5)

DuPont received information from a third party on the above-referenced substance. DuPont has reviewed the information for reportability under TSCA §8(e) and provides below a summary of the information that has been determined to meet EPA's TSCA §8(e) criteria for reporting. It is unknown whether the information reported below has been previously reported to EPA by any third party or is otherwise considered known to the Administrator under TSCA §8(e) guidance. It is also noted that the information provided below is based on a translation of a report and that the quality of the translation has not been determined.

Ames Assay

The test substance was tested for mutagenicity with the strains TA 100, TA 1535, TA 1537, TA 1538, TA 98 of Salmonella typhimurium and Escherichia coli WP2uvrA. The studies were conducted in the absence and in the presence of a metabolizing system derived from rat liver homogenate. A dose range of 5 different doses from 4 to 2500 µg/plate was used. The test substance proved to be not toxic for most of the bacterial strains at doses up to 2500 µg/plate. The dose level of 2500 µg/plate was chosen as the top dose level for the mutagenicity study.

In the absence of the metabolic activation system the test substance did not show a dose dependent influence in the number of revertants in any of the bacterial strains. In the presence of metabolic activation, treatment of the cells with the test substance resulted in relevant increases in the number of revertant colonies with the Salmonella strains TA 100, TA 1537, TA 1538 and TA 98.

Acute Oral Toxicity in Male Rats

The test substance was given in a suspension in starch mucilage in different doses from 800 to 2000 mg/kg of body weight by oral gavage to male SPF Wistar K-rats weighing between 80 - 96 g (average yielded 85 g). Ten male rats per dose level were used. The rats were fasted for 16 hours before dosing.

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The rats were observed for 7 days after treatment. Mortality occurred as follows: at 800 and 1000 mg/kg 0/10 rats died; at 1250 mg/kg 4/10 rats died; at 1600 mg/kg 7/10 rats died and at 2000 mg/kg 10/10 rats died. The animals that died showed unbalanced equilibrium, as well as on abdomen and/or on side within 1 - 24 hours after dosing. The pathological examination of the dead animals resulted in no remarkable macroscopically findings. The oral LD₅₀ for male rats was 1,418 mg/kg of body weight.

Acute Oral Toxicity in Female Rats

The test substance was given in a suspension in starch mucilage in different doses from 630 to 2500 mg/kg of body weight by oral gavage to female SPF Wistar K-rats weighing between 80 - 132 g (average yielded 93 g). Ten male rats per dose level were used. The rats were fasted for 16 hours before dosing. The rats were observed for 7 days after treatment. Mortality occurred as follows: at 630 and 1000 mg/kg 0/10 rats died; at 1250 mg/kg 6/10 rats died; at 1600 mg/kg 8/10 rats died; at 2000 mg/kg 9/10 rats died; and at 2500 10/10 rats died. The animals that died showed unbalanced equilibrium and prone position within 1 - 24 hours after dosing. The pathological examination of the dead animals resulted in no remarkable macroscopically findings. The oral LD₅₀ for female rats was 1,365 mg/kg of body weight.

Acute Subcutaneous Toxicity in Male Rats

The test substance was dissolved in warm water and was subcutaneously injected in different dosages, from 400 to 800 mg/kg of body weight, uniquely in the neck area of male SPF Wistar K-rats weighing between 104 - 160 g (average weight 136 g). Ten male rats per dose level were used. The rats were observed for 7 days after treatment. Mortality occurred as follows: at 400mg/kg 0/10 rats died; at 500 mg/kg 2/10 rats died; at 630 mg/kg 9/10 rats died; and at 800 mg/kg 10/10 rats died. The animals died the following night and showed unbalanced equilibrium and prone position and accelerated respiration. The LD₅₀ for male rats was 557 mg/kg of body weight.¹

Acute Subcutaneous Toxicity in Female Rats

The test substance was dissolved in warm water and was subcutaneously injected in different dosages, from 250 to 800 mg/kg of body weight, uniquely in the neck area of female SPF Wistar K-rats weighing between 88 - 120 g (average weight 136 g). Ten female rats per dose level were used. The rats were observed for 8 days after treatment. Mortality occurred as follows: at 250 and 400mg/kg 0/10 rats died; at 500 mg/kg 6/10 rats died; at 630 mg/kg 10/10 rats died; and at 800 mg/kg 10/10 rats died. The animals died the following night and showed unbalanced equilibrium and prone position and accelerated respiration. The LD₅₀ for female rats was 496 mg/kg of body weight.

Skin and Mucosa Tolerance in Rabbits

Five rabbits of the yellow silver race were used. For the dilution for all tests 0.9% NaCl solution was used. The examination of the test substance on skin tolerance took place in the Barail test via intracutaneous injection of 0.02 ml 5% -; 1% -; 0; 1 % -; 0.01 % - and 0.001 % solution (warm) into the shaved flank skin. As a control 0.02 ml 0.9% NaCl solution was injected. The injection of the 5% dilution led all rabbits to present at the injection points a central necroses with red halo. The use of a 1 % solution resulted in a complete redness of the injection points. The remaining injections were non-reactive.

¹ Reported as 557 mg/kg in the Summary section. Reported as 5.57 mg/kg in the body of the report.

In a further experiment with 10% and 5% diluted test substance, injections 5-times in 5 days (Mondays – to Fridays, once daily) in a quantity of over 0,5 ml on the shaved and uninjured flank skin of the rabbits. No aggravated appearance was observed.

The mucosa compatibility of the test substance was examined with the 10% and 5% concentrations by unique application of 0.1 each ml diluted sample in the conjunctiva sack of the rabbit eye. Control for possibly arising attraction features took place 1, 3, 7 and 24 hours after the application. The application of the 10% dilution led to 2/5 rabbits having complete reddening of the conjunctiva skin at approximately 7 hours. The 5% dilution was in all rabbits nonreactive.

Sincerely,

A. Michael Kaplan (duel)

A. Michael Kaplan, Ph.D.
Director - Regulatory Affairs

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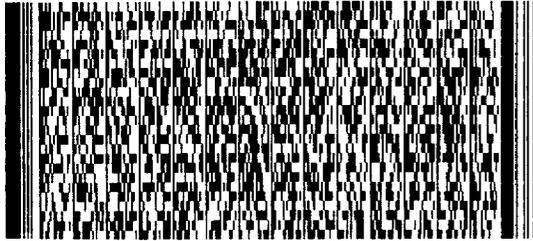


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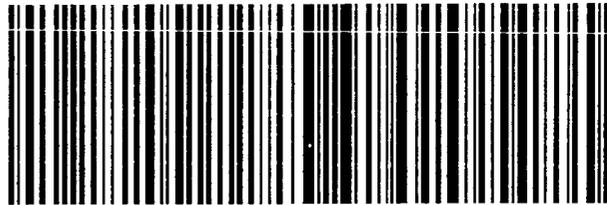
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