

ORIGINAL

**TSCA NON-CONFIDENTIAL BUSINESS INFORMATION**

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ-10-18124	<b>88110000008</b>	10 12 10

COMMENTS:

**DOES NOT CONTAIN CBI**

MR# 330486



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DuPont Haskell Global Centers  
for Health and Environmental Sciences  
1090 Elkton Road, P.O. Box 50  
Newark, DE 19714-0050

October 11, 2010

Via Federal Express

Document Processing Center (Mail Code 7407M)  
Room 6428  
Attention: 8(e) Coordinator  
Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency, ICC Building  
1201 Constitution Ave., NW  
Washington, DC 20004



Dear 8(e) Coordinator:

Dodecanedioic acid  
693-23-2



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 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.

**Subchronic Oral Toxicity Study in Rats (OECD 408):**

The sub-chronic oral toxicity of Dodecanedioic acid was evaluated in groups of 10 male and 10 female Sprague-Dawley rats. The test substance was administered orally in polyethylene glycol, at doses of 0, 50, 300 or 1800 mg/kg. Animals were observed daily 0, 1 and 2 hours after dosing for the first 45 days. Thereafter the 2 hour observation was suspended as the animals showed no signs. Detailed clinical examinations including neurotoxicity evaluation were conducted once per week. Once during week 13 of treatment sensory reactivity to stimuli of different modalities and assessment of grip strength were evaluated. Motor activity assessment was done during week 12 on 5 animals per sex and dose. Other parameters assessed included mortality, body weight, food consumption, ophthalmology, hematology, biochemistry, organ weights and histopathology.

Daily post-dose observations showed only occasional instances of rales in mid-dose and piloerection in high-dose rats. One female animal from the high-dose group died on day 7 and showed difficulty in breathing, reduced activity, hunched posture, piloerection, dyspnoea and emaciated appearance prior to death. Detailed clinical examination with neurotoxicity assessment did not show any significant signs. Neurotoxicity tests and measurements performed at the end of treatment did not show changes attributable to the test substance. A statistically significant increase in motor activity (+40 %, p<0.01) was observed in high-dose males.

No statistically significant differences in body weight gain were observed between control and treated groups. Food consumption was not affected by treatment. No findings were seen in the ophthalmoscopic examination. In clinical chemistry a statistically significant increase in albumin (males +3.8 %, females +4.5 %) and chloride (males +2.3 %; females +1.5%) was seen in the high-dose rats. The alkaline phosphatase (+24 %) and total bilirubin (+34 %) showed also a slight, but statistically significant increase in high-dose males. These changes were within historical control values and, therefore, they are considered to be of no toxicological relevance.

There was a statistically significant increase in hematocrit in all treated female groups (low-dose +3.4 %, mid-dose +4.7 %, high-dose +5.2 %) and in red blood cell count (mid-dose +4.5 %, high-dose +4.0 %) and hemoglobin (mid-

**CONTAINS NO CBI**

dose +3.6 %, high-dose +4.7 %) in mid- and high-dose females. These values were still within the range of historical control data and considered to be solely due to unusually low and consistent values in the control group, i.e. of no toxicological relevance.

Some statistically significant increases in organ weights observed in high-dose rats were considered to be of no toxicological significance as they were not related to any morphological changes and were well within the range of historical control data: epididymis (males) relative +8.1 %, heart (females) absolute +6.3 %, relative +10 % (both also significant at low dose, not at mid dose) kidney (females) +6.3 % adrenal (females) +11 %. Dark/red color of several organs and tissues, as well as decreased size of the spleen and the thymus were observed at necropsy of the high-dose female that died on day 7. No macroscopic finding was described at post mortem examination of the animals sacrificed at termination that could be considered correlated with the administration of the test substance.

Congestion of several organs and atrophy of the spleen and the thymus were observed at the microscopic evaluation performed on the animal found dead. No significant difference was detected in the incidence of the pathological findings when treated animals were compared to controls.

Sincerely,

A handwritten signature in cursive script that reads "A. Michael Kaplan".

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

AMK/RV: clp  
(302) 366-5260



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