

ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8FHG-10-17815	89100000292	8/3/10

COMMENTS:

DOES NOT CONTAIN CBI

328909



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

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August 02, 2010

Via Federal Express

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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

Public Copy
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8EHQ-0810-17815B



Dear 8(e) Coordinator:

1,4-Butanediol (CAS Number 110-63-4)
8EHQ-10-17815

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.

Test substance: 1,4-Butanediol (CAS Number 110-63-4)

• Acute Oral Toxicity Study

A test group consisting of 5 rats/sex was treated by single gavage dose with an aqueous solution of the test substance. The animals were observed for mortality and for clinical symptoms of toxicity. The rats were weighed prior treatment and thereafter, day 3, day 7 and day 13 post-treatment. At the end of the observation period of 14 days, the surviving animals were sacrificed for the purpose of necropsy; animals that died during the observations period also were subjected to necropsy. Clinical signs observed in male rats included dyspnea, apathy, abnormal position, staggering, atony, unusual pain reflex, unusual cornea reflex, narcotic-like state, tremor, scrubby fur, exsiccosis, exophthalmus, and poor general state. In female rats, clinical sign included dyspnea, apathy, abnormal position, staggering, atony, unusual pain reflex, unusual cornea reflex, narcotic-like state, tremor, spastic gait, scrubby fur, loss of hair, exsiccosis, exophthalmus, and poor general state. The LD50 for female rats was 1670 mg/kg body weight and for male rats was 1350 mg/kg body weight.

DCN:8910000292



- Acute Inhalation Toxicity Study

An acute inhalation toxicity study was conducted in accordance to OECD guideline 403. Male and female Wistar rats were exposed by inhalation to the test substance at 5.1 mg/L over a 4-hour period. All animals survived. The animals showed accelerated or shallow respiration during the 4 hour exposure and on the test day. Additionally on the test day nasal discharge, ruffled fur, staggering unsteady gait and deteriorated general state was noted. Ruffled fur continued on day 1 after exposure and on day 2 all animals were free of symptoms.

- Acute Dermal Toxicity Study

In a dermal LD50 study, 5 male and 5 female rats were dosed at 2000 mg/kg of body weight. The test material remained in contact with the skin for 24 hours. After 24 hours, the skin was washed with warm water. Observations for mortality, local reactions, and behavioral abnormalities were continued for a total of 14 days following the skin applications. All animals survived. Clinical signs included dyspnoea, unsettled behavior and poor general state within the first 2 hours of exposure.

- Human Exposure

A U.S. FDA presentation reported that at least three people had died and more than 100 had become ill after taking unregulated new products, which are listed as "party drugs" on internet sites, advertised in muscle-building magazines, and sold in health food stores as dietary supplements to aid in sleep. These products contain the test substance. According to FDA, the test substance can cause dangerously low respiratory rates, unconscious, vomiting, seizures and death. In addition, this substance may also increase the effects of alcohol, and is even more dangerous when consumed with other depressant drugs.

Sincerely,

A. Michael Kaplan
(dud)

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

AMK: clp
(302) 366-5260

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Pa

From: Origin ID: ZWIA (302) 773-0071
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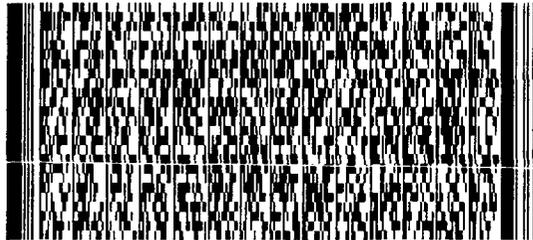
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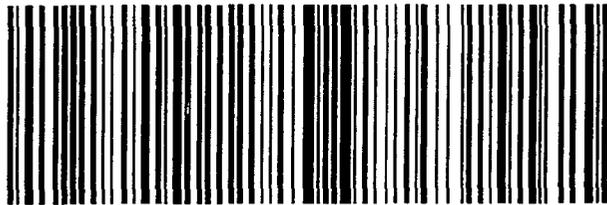


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