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Office of Pollution Prevention and Toxics
Environmental Protection Agency
401 M Street, S. W.
Washington, D.C. 20460



88940000264

Attn.: Section 8(e) Coordinator

Re: Substantial Risk Notification
Pursuant to TSCA Section 8(e)

Dear Sir:

This Substantial Risk Notification is being submitted in accordance with Section 8(e) of the Toxic Substances Control Act (TSCA) by Degussa Corporation. In response to a bona fide intent to import, we were informed that the substance was listed on the confidential portion of the TSCA Inventory (EPA Control No. 528400314).

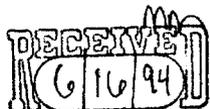
The chemical name is 1-Dodecanaminium, N-(3-chloro-2-hydroxypropyl)-N,N-dimethyl-chloride (which we identify by the trade names QUAB 342 and Lauryl QUAB) CASRN 41892-01-7.

We have just been made aware of some toxicity studies which can be considered to be reportable under TSCA Section 8(e) because of certain neurotoxic effects. Although we do not believe that the results reasonably support the conclusion that the substance presents a reasonable risk of injury to the health or the environment, based on EPA's guidelines of June 1991, we are submitting them to the TSCA Section 8(e) Office.

A summary of each study and a printout from the STN Chemical Abstracts Service Registry File follows; copies of the studies are attached. Because the oral and dermal toxicity reports are in German, we have provided English translations of the summaries.

Acute Oral Toxicity Study in Rats

Dosage/route/duration: The test material was administered by gavage diluted and undiluted to male and female rats at a volume between 2.15 and 4.65 ml/kg. Post-exposure observation was 14 days.



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Results: Intoxication was characterized by disturbance of the autonomic nervous system and the general condition (tremor, stilted gait, sunken sides or abdominal distension, salivation, ruffled fur, diarrhea, loss of body weight). Ante mortem loss of reflexes, convulsions, mydriasis and dyspnoea occurred in some individuals. The course of intoxication was acute to prolonged.

At necropsy of the deceased animals, stomach and intestine contained a colorless, red or yellow liquid. The mucosa of these organs was reddened. In one animal the stomach was perforated. In some cases gathering of liquid was detected in abdominal and thoracic cavity.

The LD₅₀ value for female rats was 3066 mg/kg and for male rats 2332 mg/kg.

Acute Dermal Toxicity Study In Rabbits

Dosage/route/duration: The test material was administered undiluted to the dorsal skin of male and female rabbits at doses between 931 and 4321 mg/kg for 24 hours under occlusive conditions. The post-exposure observation was 14 days.

Results: Intoxication was characterized by tremor, ruffled fur, and reduction of body strength. Intoxication was prolonged. Deaths occurred between 2 and 7 days after application. At the application site grey discoloration, reddening, and eschar formation occurred.

At necropsy unspecific changes in kidneys, liver, spleen, lungs, heart and small intestine were observed.

The LD₅₀ value for male and female rabbits was 2523 mg/kg.

In Vitro Ames Test

Salmonella typhimurium strains TA 98, TA 100, TA 1535, TA 1537, and TA 1538 were tested with and without liver microsomal activation system (Arochlor induced rats) at concentrations between 1.0 to 216 micrograms per plate.

At a concentration of 46.4 microgram/plate a weak increase (< x 2) was observed in the test strain TA 1538 in the absence of S9-mix. At higher concentrations, the number of revertants were decreased. Cytotoxicity was observed at 46 microgram/plate and at higher concentrations.

In Vivo Micronucleus Test in Mice

21.5 mg/kg (males) or 31.6 mg/kg (females) of the test substance were administered intraperitoneal to mice. No significant increase in micronucleated polychromatic erythrocytes was observed in both male and female mice, respectively males and females combined, at 24, 48 or 72 hours after administration.

Sincerely,



John Lewinson, Ph.D.
Manager, Product Regulatory Compliance

JL-94-178

cc: R. Marion, DCA
Dr. Pieter, DCRP
B. Santoro, DCRP