

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
MEDICAL TOXICOLOGY BRANCH

SUMMARY OF TOXICOLOGY DATA
OXYDIETHYLENE BIS (ALKYL DIMETHYL AMMONIUM CHLORIDE)
Alkyl Derived from Coconut Oil Fatty Acids

Chemical Code # 001362, Tolerance # 50351
SB 950 # 457
Original date: 04/30/02

I. DATA GAP STATUS

Chronic toxicity, rat:	Data gap, no study on file
Chronic toxicity, dog:	Data gap, no study on file
Oncogenicity, rat:	Data gap, no study on file
Oncogenicity, mouse:	Data gap, no study on file
Reproduction, rat:	Data gap, no study on file
Teratology, rat:	No data gap, no adverse effect
Teratology, rabbit:	Data gap, no study on file
Gene mutation:	Data gap, inadequate study, no adverse effect indicated
Chromosome effects:	No data gap, no adverse effect
DNA damage:	Data gap, inadequate study, no adverse effect indicated
Neurotoxicity:	Not required at this time

Toxicology one-liners are attached.

All record numbers through 114149 examined.

** Indicates an acceptable study.

Bold face indicates a possible adverse effect.

File Name: T020430.

Original by: J. Kishiyama and Gee, 4/30/02

NOTE: Oxyethylenebis(alkyl dimethyl ammonium chloride), alkyl derived from coconut oil fatty acids, is used primarily for aquatic, industrial sites and has been grouped by US EPA with a series of aliphatic alkyl quaternaries (Rainbow Book, Spring, 1998) didecyl dimethyl ammonium chloride (CC: 1682) as the lead chemical. All data gaps have been filled for that active ingredient. See the Summary of Toxicology Data, dated February 14, 1996 in D50350.

II. TOXICOLOGY ONE-LINERS AND CONCLUSIONS

These pages contain summaries only. Individual worksheets may contain additional effects.

COMBINED, RAT

No study submitted

CHRONIC TOXICITY, RAT

No study submitted

CHRONIC TOXICITY, DOG

No study submitted

ONCOGENICITY, RAT

No study submitted

ONCOGENICITY, MOUSE

No study submitted

REPRODUCTION, RAT

No study submitted

TERATOLOGY, RAT

** 50351 - 004 114149 Rodwell, D. E. "Teratology Study in Rats with CDQ." (Springborn Life Sciences, Inc., SLS Study No. 3138.27, September 1, 1988.) CDQ (lot no. 6-13567, 36% purity by weight, sp. gr. 0.92) was administered by gavage at doses of 0 (distilled water), 40, 160, or 400 mg/kg (doses not corrected for purity) during gestation days 6 through 15 to 28 mated Sprague-Dawley female rats/group. CDQ doses of 160 and 400 mg/kg increased the incidences of rales, salivation, rough coat and unkempt appearance, urine and fecal staining, dark material around mouth and nose and clear nasal discharge. Body weight change and food intake were lower for the high dose group, reaching statistical significance early in the dosing period, days 6 - 9. This lower gain was also reflected in the overall gain days 6 - 16 and 0 - 20. No significant developmental effects were reported. Maternal NOEL = 40 mg/kg/day (clinical signs). Developmental NOEL = 400 mg/kg/day. ACCEPTABLE with no adverse effect. (Kishiyama and Gee, 4/23/02).

TERATOLOGY, RABBIT

No study submitted

GENE MUTATION

50351 - 002 062452 Jagannath, D. R. "Mutagenicity Test on CDQ in the Ames *Salmonella*/Microsome Reverse Mutation Assay". (Hazleton Laboratories America, Inc., HLA Study No.: 9972-0-401, September 8, 1987.) CDQ (no lot number or purity), was tested at concentrations ranging from 0.001 μ l to 0.25 μ l/plate, with and without rat liver metabolic activation (S9 Mix) for mutagenic potential using *Salmonella typhimurium* strains TA 1535, TA1537, TA1538, TA98, and TA100. Concentrations used were selected based on a preliminary cytotoxicity assay which tested from 0.02 to 150 μ l/plate. At 0.07 to 0.59 μ l/plate, microcolonies were noted. At higher concentrations, the background lawn was clear. In the definitive trials, there were triplicate plates per concentration and two trials were run. Positive controls were functional. There was no significant increase in revertants. UNACCEPTABLE (test article characterization). Upgradeable. (Kishiyama and Gee, 4/23/02).

CHROMOSOME EFFECTS

** 50351 - 002 062453 Murli, H. "Mutagenicity Test on CDQ in an *In Vitro* Cytogenetic Assay Measuring Sister Chromatid Exchange Frequencies in Chinese Hamster Ovary (CHO) Cells." (Hazleton Laboratories America, Inc., HLA Study No.: 9972-0-438, August 10, 1987.) CDQ (lot no. 6-13567, 36% by wt.) was tested at concentrations ranging from 0.167 through 5020 μ g/ml with and without metabolic activation (S9 Mix) for induction of sister chromatid exchanges in Chinese hamster ovary (CHO-WBL) cells. There was a single culture per concentration with fifty cells scored per culture for sister chromatid exchanges. Mitomycin C and cyclophosphamide were the positive controls without and with activation, respectively. Cyclophosphamide was only marginally functional. CDQ treatments (with and without S9 Mix) did not induce sister chromatid exchanges in Chinese hamster ovary cells. ACCEPTABLE with minor deficiencies. (Kishiyama and Gee, 4/23/02).

DNA DAMAGE

50351 - 002 062451 Cifone, M. A. "Mutagenicity Test on CDQ in the Rat Primary Hepatocyte Unscheduled DNA Synthesis Assay." (Hazleton Laboratories America, Inc., HLA Study No.: 9972-0-447, November 2, 1987) CDQ (36% by weight, sp. Gr. 0.92) was tested at concentrations ranging from 0.251 to 10.0 μ g/ml for DNA damage as measured by UDS in primary rat hepatocytes *in vitro*, using autoradiography. Concentrations of 25.1 μ g/ml and higher were too toxic for evaluation. Fifty cells on each of three coverslips were scored for grain counts. Cytotoxicity was determined by trypan blue exclusion, using duplicate coverslips. There were no significant changes in the nuclear labeling of rat primary hepatocytes. UNACCEPTABLE (only summary data were presented in a single table, no individual cell or coverslip data, no mean cytoplasmic or nuclear grain counts, GLP and QA statements were unsigned). Upgradeable. (Kishiyama and Gee, 4/22/02).

NEUROTOXICITY

DPR MEDICAL TOXICOLOGY

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Not required at this time.