

US EPA ARCHIVE DOCUMENT

October 12, 1995

MEMORANDUM

SUBJECT: New Chemical Screen for Didecyldimethyl Ammonium Carbonate and Didecyldimethyl Ammonium Bicarbonate (BARDAC 22C50™) - PC Code 069208.
DP Number: D218364.

FROM: Barbara Madden, Biologist
Registration Section
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

THROUGH: Karen Whitby, Section Head
Registration Section
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Health Effects Division (7509C)

TO: Karen Leavy/Marion Johnson PM 31
Anti-Microbial Branch
Registration Division (7505C)

The Health Effects Division (HED) has been asked to conduct a new chemical screen on data submitted by Lonza Inc. to support the registration (EPA File Symbol 6836-EGA) of the new chemical didecyldimethyl ammonium carbonate and didecyldimethyl ammonium bicarbonate (BARDAC 22C50™) - Pesticide Chemical Code 069208.

Lonza Inc. submitted three acute toxicology studies using the active ingredient didecyldimethyl ammonium carbonate [§81-1 (MRID 436491-03), §81-5 (MRID 436491-04), and §81-6 (MRID 436491-05)]. The company requested waivers from the requirement of data for the remaining acute toxicological data guideline requirements §81-2, §81-3, and §81-4. The company also cited previously submitted data to support the required subchronic and chronic data requirements. Data cited were submitted to support the registration of didecyldimethyl ammonium chloride (BARDAC 2280™). The company states that didecyldimethyl ammonium chloride (BARDAC 2280™) is very similar to didecyldimethyl ammonium carbonate and didecyldimethyl ammonium bicarbonate (BARDAC 22C50™).

For the purposes of the new chemical screen only HED has determined that all data requirements have been addressed. HED will not determine if the waiver requests and data cited will be accepted to support the registration of didecyldimethyl ammonium carbonate and didecyldimethyl ammonium bicarbonate (BARDAC 22C50™) until the package is put into full review.

In order to determine if the data cited will be accepted to support the registration of didecyldimethyl ammonium carbonate

and didecyldimethyl ammonium bicarbonate (BARDAC 22C50™) toxicology will need the following information.

1. Comparison of the pH for didecyldimethyl ammonium carbonate and didecyldimethyl ammonium bicarbonate (BARDAC 22C50™) versus didecyldimethyl ammonium chloride (BARDAC 2280™).
2. Comparison of the manufacturing process for didecyldimethyl ammonium carbonate and didecyldimethyl ammonium bicarbonate (BARDAC 22C50™) versus didecyldimethyl ammonium chloride (BARDAC 2280™).
3. Comparison of any contaminants or byproducts from the processing of didecyldimethyl ammonium carbonate and didecyldimethyl ammonium bicarbonate (BARDAC 22C50™) versus didecyldimethyl ammonium chloride (BARDAC 2280™).

This information should accompany the bean sheet requesting review of the data.

Below is list of data cited to support the registration of didecyldimethyl ammonium carbonate and didecyldimethyl ammonium bicarbonate (BARDAC 22C50™). The data was originally submitted to support registration of didecyldimethyl ammonium chloride (BARDAC 2280™).

Guideline No.	Kind of Data	MRID #
82-1	90-day feeding study - rodent	409663-02
82-1	90-day feeding study - non-rodent	402629-01 & 419704-01
82-3	90-day dermal	408952-03 & 413059-01
83-1	Chronic feeding - rodent	418023-01
83-1	Chronic feeding - non-rodent	419704-01
83-2	Oncogenicity study - rat	419651-01
83-2	Oncogenicity study - mouse	418023-01
83-3	Teratogenicity - rodent	418867-01
83-3	Teratogenicity - non-rodent	410187-01
83-4	Reproduction, 2-generation	418045-01
84-2(a)	Gene mutation	408952-02
84-2(b)	Structural chromosomal aberration	407058-01 & 412526-01
84-4	Other genotoxic effects	408952-01 & 407058-02
85-1	General metabolism	416171-01 & 413851-01