CASWELL FILE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 2 2 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Poly (hexamethylenebiguanide); Baquacil: Review of Data Waiver Requests Submitted by the Registrant.

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and

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Registrant: ICI Specialty Chemicals, Wilmington, Delaware

Action Requested: Review of data waiver requests submitted by the registrant.

Data Summary:

ICI Specialty Chemicals submitted requests for data waivers in their 90-Day response to the Phase IV DCI for baquacil. The waiver requests included the following toxicology data requirements:

§81-3	Acute Inhalation Toxicity in Rats
§82-1(a)	Subchronic Oral Toxicity in Rodents
§82-1(b)	Subchronic Oral Toxicity in Non-rodents
§82-3	Subchronic Dermal Toxicity
§83-3(c)	Developmental Toxicity in Mice

The Agency's reponse to each waiver request is discussed below:

§81-3

The registrant states that the technical product or end use product is manufactured as a non-volatile liquid. Thus, no respirable particles are generated during manufacture, handling, or storage of the product. End uses do not involve spray applications and exposure by this route is not a consideration.

Based upon these data as submitted by the registrant, Toxicology Branch II has no objection to the granting of a data waiver for an acute inhalation toxicity study in rats.

§82-1(a), §82-1(b)

The registrant requests data waivers for these subchronic studies based upon the fact that product reregistration will be supported by a chronic database.

Toxicology Branch II's recommendation is reserved, pending receipt and review of acceptable chronic studies in support of reregistration of PHMB.

§82-3

The registrant stated that since PHMB will be supported by a chronic database, a 21-day dermal toxicity study will be sufficient for this requirement.

Toxicology Branch II acknowledges that a 21-day dermal toxicity study will be adequate in this respect. A recommendation for a data waiver for a 90-day dermal toxicity study is reserved pending receipt and review of an acceptable 21-day dermal toxicity study.

§83-3(c)

The registrant stated that the rat teratology study will be upgraded, and a new rabbit teratology study will be submitted.

Toxicology Branch II's recommendation for a data waiver for a mouse teratology study is reserved pending receipt and review of acceptable rat and rabbit teratology studies.

Conclusions:

Data waiver requests submitted by ICI Specialty Chemicals for baquacil were presented before the FIFRA '88 committee in a meeting held on 9/16/92. The recommendations of the committee are in agreement with those of Toxicology Branch II.

Toxicology Branch II has no objection to granting of a data waiver for an acute inhalation toxicity study in rats. Recommendations are reserved for data waivers requested for guidelines § 82-1(a), §82-1(b), §82-3, and §83-3 at this time pending receipt and review of acceptable chronic and developmental toxicity studies by the registrant.