CASWELL FILE

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

7/2/92

JUL 2 1992

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: PHMB (Vantocil P). Response to Questions Concerning 21-Day Dermal Study.

Tox. Chem. No. 676
Project No. D177669

TO: Katherine Scanlon, PM Team #
Special Review and
Reregistration Division (H7508W)

FROM: Pamela M. Hurley, Toxicologist Pamela M. Hurley
Section I, Toxicology Branch I 5/6/92
Health Effects Division (H7509C)

THRU: Roger L. Gardner, Section Head
Section I, Toxicology Branch I Roger Gardner 6-2-92 KB 6/19/92
Health Effects Division (H7509C)

Submission: S417162

Background and Request:

ICI Americas Inc. is proposing to start a 21-day dermal study on PHMB. The technical material (Vantocil) is an aqueous solution with a PHMB concentration of 20% (w/v). The Registrant has noted that for compounds of relatively low toxicity, a limit test may be conducted with a dose of 1000 mg/kg/day. They are seeking clarification from the Agency whether the limit dose should be 1000 mg/kg Vantocil P/day or 1000 mg/kg PHMB/day. If the latter is the case, because the technical material is a 20% concentration, then it would require dosing between 1.0 - 1.5 ml for each application. The Registrant's experience has found that the maximum volume that can be accurately applied for aqueous solutions is approximately 0.8 ml, which equates to approximately 640 mg PHMB/kg. The Registrant further requests whether or not the Agency has any objection to a study with the selection of the highest dose level based on the maximum volume that can be accurately applied.

Toxicology Branch Response:

The Toxicology Branch (TB-I) has reviewed the Registrant's questions concerning the 21-day dermal study and has the following response: the maximum dose should be based on 1000

mg/kg PHMB/day; and in this particular case, TB-I has no objection to basing the selection of the highest dose level on the maximum volume that can be accurately applied. Our reasoning is based on information that was provided to us in a telephone conversation with the Registrant representative:

- The technical material is never in a form that is greater than a 20% concentration because in higher concentrations it becomes a deliquescent gum.
- The acute dermal toxicity is greater than 2.0 ml/kg.
- No one will ever be exposed to a concentration greater than 20%.

cc: M. Ioannou

DP BARCODE: D177669 REREG CASE # 3122

CASE: 816384 DATA PACKAGE RECORD DATE: 05/04/92
SUBMISSION: S417162 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION ACTION: 629 GENERAL CORR - REREGIS
CHEMICALS: 111801 Poly(iminoimidocarbonyliminoimidocarbonyliminohexa %

ID#: 111801-010182
COMPANY: 010182 ICI AMERICAS INC
PRODUCT MANAGER: 52 ROOM:
PM TEAM REVIEWER: LINDA DELUISE 703-308-8065 ROOM: CS1 3F3
RECEIVED DATE: 05/04/92 DUE OUT DATE: 08/02/92

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 177669 EXPEDITE: N DATE SENT: 05/04/92 DATE RET.: / /
CHEMICAL: 111801 Poly(iminoimidocarbonyliminoimidocarbonyliminohexamethylene
DP TYPE: 999 Miscellaneous Data Package
ADMIN DUE DATE: 07/18/92 CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : HED	/ /	/ /
BRAN: TB-1	/ /	/ /
SECT: RS-1	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

ATTENTION: Pam Hurley. Please respond to the question from the registrant regarding the 21-day dermal study on Vantocil P. You already have the necessary data. Return to Kathryn Scanlon (H7508W). Thanks.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

ICI AMERICAS INC.
FAX MESSAGE

DATE: April 23, 1992

TO: Dr. Jim Rowe

LOCATION: EPA

fax (703) 305-5147

office phone (703) 305-5664

FROM: MARK E. BURT
ICI SPECIALTIES
SAFETY, HEALTH & ENVIRONMENT GROUP
DELAWARE CORPORATE CENTER I
ICI AMERICAS INC.
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TELEPHONE (302) 886-5579
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NUMBER OF PAGES (INCLUDING THIS PAGE): 2

Dear Dr. Rowe:

Attached, as we discussed yesterday, is the procedure for applying test material in the 21-day dermal study.

I look forward to receiving your comments.

Thanks for your help.

Sincerely,

Mark E. Burt

RIN 4292-93 BAQUACIL 111801

Page_____ is not included in this copy.

Pages 5 through 7 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

✓ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
