



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

7/2/92

JUL 2 1992

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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

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 *Roger Gardner*
Section I, Toxicology Branch I *6-2-92*
Health Effects Division (H7509C)

KRB
6/19/92

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:

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

cc: M. Ioannou

DP BARCODE: D177669

REREG CASE # 3122

CASE: 816384
SUBMISSION: S417162

DATA PACKAGE RECORD
BEAN SHEET

DATE: 05/04/92
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
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
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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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NUMBER OF PAGES (INCLUDING THIS PAGE): 2

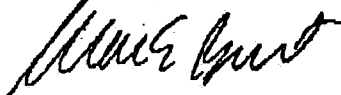
Dear Dr. Rowe:

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

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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.