



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

JAN 3 2001

OFFICE OF

PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of a Health Risk Assessment for PHMB (Vantocil IB) Used on 100% Cotton Textile Application-Systemic Toxicity by an Infant Sucking Textile

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DP Barcode: D268348

Pesticide Chemical No.: 111801

Review Time: 15 Hours

MRID #: 45877-01

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Action Request:

The Risk Assessment and Science Support Branch (RASSB) has been asked to review a risk assessment study submitted by the Avecia Inc. in support of an amendment to add the use of Vantocil IB microbiocide on apparel items.

The following information may be used to identify this study:

Study Title: Health risk assessment of PHMB in 100% cotton textile applications-systemic toxicity by an infant sucking a textile (initially unwashed, subsequently washed). B.S. Blackhouse, 2000. Avecia Limited, UK.

Background and Discussion:

Vantocil IB is used as a preservative in a wide variety of applications including:

- Silicones,
- Tunnel pasteurization,
- Preservation of aqueous industrial chemicals,
- Leather processing,
- Aqueous mineral slurries,
- Aqueous based adhesives,
- Industrial electrocoats,
- Preservation of fresh animal hides and skins,
- Cellulosic materials and textiles.

Avecia Inc. has applied for a label amendment to add apparel items to direction or use of Vantocil IB. The assessment considers the potential for systemic toxicity by an infant sucking 100% woven cotton fabric, containing 0.4% PHMB (2% Reputex 20), based on the estimated quantity of PHMB available. The data used are taken from ASG project entitled: measurement of Poly (Hexamethylene biguanide) [PHMB] in cotton and polyester cloths. Vantocil IB is an aqueous solution of polyhexamethylene biguanide hydrochloride and is soluble in water and stable under normal conditions of storage.

The apparel items or clothing which will be added are:

- slacks, shirts, underwear, sweatshirts, sweat pants, oven mits, slippers, bathrobes, gloves, hats, scarves, jackets, diapers and incontinence pad cover stock.

Conclusions:

The risk assessment study and calculations which are submitted by the registrant need further review and evaluation. According to a memorandum by RASSB toxicologist Dr. Jonathan Chen (a copy of the memorandum is attached) :

11. PHMB is a human skin sensitizer and ,
12. There are concerns with long term chronic exposure of PHMB through dermal exposure route. PHMB may cause cancer through dermal exposure.

The risk assessment provided by the registrant does not address the aforementioned issues in regards to the use of PHMB on textiles. Further, because it is not possible to predict whether a threshold level exists for induction and subsequent immunologic reaction (skin sensitization or possibly other toxic manifestations), RASSB is unable to quantify potential risks at this time.

File: C:\myfiles\2000reports\Review of a Health Risk Assessment for PHMB (Vantocil IB) used on 100% cotton Textile (D268348).wpd

CC: Siroos Mostaghimi/RASSB/AD
Chemical files