US EPA ARCHIVE DOCUMENT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Response to SC Johnson Email Dated April 22, 2003 Regarding UICK-T (EPA File Symbol 4822-LEA), Containing 8 % p-Methane-3,8-diol (PC Code 011550) as Active Ingredient.

FROM: Mary Clock-Rust, Biologist Mary Clock Rust
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division

THRU: Russell S. Jones, Ph.D., Biologist Russell S. Jones 5/15/03
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division

TO: Todd Peterson, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides &Pollution Prevention Division

ACTION REQUESTED

This memorandum addresses points made in an email message BPB received from SC Johnson (Jean M. Fugate to Todd Peterson, 4/22/03). In the email, SCJ replied to several conclusions made by BPB in a recent review of product chemistry data and eye irritation studies in support of the registration of UICK-T (EPA File Symbol 4822-LEA) (*Registration of UICK-T (EPA File Symbol 4822-LEA), Containing 8 % p-Methane-3,8-diol (PC Code 011550) as Active Ingredient. Review of Product Chemistry Data and Eye Irritation Study. D282656. Case No. 071468. Submission No. S613609. MRID Nos. 45615201 - 45615205.* M. Clock-Rust. 04/30/03)

CONCLUSIONS

The three main issues raised in the email included details regarding CSFs for the basic and alternate formulations of UICK-T, physical and chemical properties and bio-efficacy data. Each point is addressed below.

1. Clarification and Details about the CSFs for the basic and alternate formulations of UICK-T.

BPB has reviewed Confidential Statements of Formula (CSFs) associated with this registration and determined that with significant corrections, the CSFs are acceptable. BPB's conclusions are summarized below.

Inert ingredient information not included.

Note: The written explanation of the expanded certified limits for the active ingredient (p-menthane-3,8-diol technical) are acceptable.

Corrections needed for **CSFs for ALL Formulations** (Basic and Alternates):

a) The complete file symbol or registration number must appear in item 4.
b) [redacted]
c)

The following specific corrections are also needed for two of the **Alternate Formulations**:

Formula **30249A** and Formula **30252A**:

[redacted]

2. Physical/Chemical properties.

BPB requested a one-year storage stability and corrosion characteristics study.

SC Johnson responded to BPB's request by sending in the requested data on storage stability and corrosion characteristics (MRID 45912501). The registrant's response is acceptable and satisfies the data requirement. No further data are necessary.

3. Bio-efficacy Issue.

BPB requested that the registrant submit the bio-efficacy study in which UICK-T was used to apply the formulation to the skin at the rate of 1.92 mg/cm^2.

SC Johnson provided BPB with a summary page from the study report showing the successful delivery of the formulation using the towelette (UICK-T) in 9 subjects. The average amount delivered to skin surface was 1.92 mg/cm^2. The target amount, was approximately 1 gram per 600 cm^2, or 1.67 mg/cm^2. Therefore, according to SCJ's testing of UICK-T, the towelette is an adequate means for delivery of the formulation. BPB has concluded that no further data are necessary.

cc: M. Clock-Rust, T. Peterson, BPPD Subject File
M. Clock-Rust: (703) 308-2718: 05/09/03