

US EPA ARCHIVE DOCUMENT



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

April 14, 1999

MEMORANDUM:

Subject: Acute Toxicity Review for EPA Reg. No.: 71227-E / Zeomic type AJ10 N Silver
DP Barcode: D251494
Case No: 064337

To: Marshall Swindell, PM 33 / Tony Kish
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist
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Through: Karen Hicks, Team Leader
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Applicant: Shinagawa Fuel Co., Ltd.

FORMULATION FROM LABEL:

| | |
|------------------------------|-----------------|
| <u>Active Ingredient(s):</u> | <u>% by wt.</u> |
| Silver | 2.7 |
| <u>Other Ingredient(s):</u> | 97.8 |
| Total: | 100.0% |

BACKGROUND: Shinagawa Fuel Co., Ltd., has cited an acute oral toxicity study, an acute dermal toxicity study and a primary skin irritation study to support "Zeomic type AJ10 N Silver". These studies were conducted using, and reviewed in support of, another Shinagawa product, "Zeomic Type AJ10 D Silver Zeolite A", EPA File Symbol 71227-R. That review was completed by ESSB/AD on 3/11/99. The MRID numbers are 446644-01 and 446644-02.

This submission also includes a request for data waivers. This report requests, among other things, the waiver of the acute inhalation toxicity, primary eye irritation and dermal sensitization studies. This report was not assigned a MRID number. Please refer to the attached sheet from Shinagawa's application for pesticide registration.

RECOMMENDATIONS: ESSB findings are:

1. ESSB/AD finds the formulation of EPA File Symbol 71227-E to be toxicologically similar to that of EPA File Symbol 71227-R. Thus, acute toxicity data conducted on File Symbol 71227-R may be used to support the registration of File Symbol 71227-E.
2. The acute oral toxicity, acute dermal toxicity and primary skin irritation studies are adequate to support File Symbol 71227-E.
3. The waiver of the primary eye irritation study is denied. There are many pesticide products that are primary eye irritants that demonstrate little or no irritation in the primary skin irritation study (as did this product).
4. The waiver of the acute inhalation toxicity study is denied. The basis that this product exhibited little or no toxicity in the acute oral and dermal toxicity tests is insufficient. There are known pesticide products that pose a greater inhalation hazard than they do by oral or dermal exposure.
5. The waiver of the dermal sensitization study is denied. The request gave no support for the waiver of the dermal sensitization study.

The acute toxicity profile for reg. no. 71227-E is currently:

| | | |
|---------------------------|-----|-------------|
| acute oral toxicity | IV | acceptable |
| acute dermal toxicity | III | acceptable |
| acute inhalation toxicity | | Outstanding |
| primary eye irritation | | Outstanding |
| primary skin irritation | IV | acceptable |
| dermal sensitization | | Outstanding |

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LABELING:

No precautionary labeling can be recommended at this time due to the outstanding acute inhalation toxicity, primary eye irritation and dermal sensitization studies.