DP BARCODE: D251466

CASE: 064467 DATA PACKAGE RECORD DATE: 12/08/98
SUBMISSION: S549706 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 165 NEW PROD-OC-MINOR CHG
CHEMICALS: 072503 Silver nitrate 10.0000%

ID#: 071227-R Zeomic Type AJ10 D Silver Zeolite A
COMPANY: 071227 SHINAGAWA FUEL CO., LTD.
PRODUCT MANAGER: 33 MARSHALL SWINDELL 703-308-6341 ROOM: CS1 6B
PM TEAM REVIEWER: TONY KISH 703-308-9443 ROOM: CS1 3W69
RECEIVED DATE: 09/10/98 DUE OUT DATE: 03/19/99

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 251466 EXPEDITE: Y DATE SENT: 12/07/98 DATE RET.: / /
CHEMICAL: 072503 Silver nitrate
TYPE: 001
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : AD	/ /	/ /
BRAN: EASSB	/ /	/ /
SECT: CTT	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

ADMIN DUE DATE: 05/06/99
NEGOT DATE: / /
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

KAREN: Note that the admin due date is way after the EPA due date. I spoke with you about this "problem" submission recently. We thought it would not need an acute tox review because the silver RED waives all generic acute tox. Tim McMahon suggested we put it into review because the EUP acute tox can differ from just the silver tox.

Attached are three acutes: oral and dermal (MRID 446644-01); primary skin (MRID 446644-02); along with a waiver request for the other three acutes (no MRID), CSF, label. Any questions, call Tony Kish. THANKS!

Your review covers three registrations 71227-R, 71227-E, and 71227-G. There are three BEAN sheets to reflect this. This one, D251494 (71227-E), and D251497 (71227-G). Any questions, call Tony Kish. THANKS!

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

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

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
250942	EASSB/CTT	11/16/98	04/15/99	Y	Y	Y

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

March 11, 1999

MEMORANDUM:

Subject: Acute Toxicity Reviews for EPA Reg. Nos.: 71227-R / Zeomic Type AJ10 D
DP Barcode: D251466
Case No: 064467

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

From: Ian Blackwell, Biologist
Efficacy Evaluation Team
Efficacy and Science Support Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Efficacy and Science Support Branch
Antimicrobials Division (7510C)
3/11/99

Michele Wingfield, Branch Chief
Efficacy and Science Support Branch
Antimicrobials Division (7510C)

Applicant: Shinagawa Fuel Co., LTD

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Silver ~~nitrate~~	~~10~~ 2.5%
Other Ingredient(s):	~~90~~ 97.5%
Total:	100%

BACKGROUND: Shinagawa Fuel Co., LTD., has submitted a set of acute toxicity irritation studies to support the registration of three of their products: Zeomic Type AJ10 D, Zeomic Type AJ10 N and Zeomic Type AJ10 H. The submitted studies include acute oral toxicity, acute dermal toxicity and primary skin irritation studies. The MRID numbers are 446644-01 (one report including both the acute oral and acute dermal toxicity studies) and 446644-02. The request for data waivers came in a report form, but was not assigned an MRID. (In this submission, the acute dermal toxicity study is identified as a percutaneous administration study and the primary skin irritation study is identified as an acute dermal irritation study.)

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.

RECOMMENDATIONS: ESSB findings are:

1. The acute oral toxicity, acute dermal toxicity and primary skin irritation studies are acceptable.

2. 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).

3. 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 pesticide products that pose a greater inhalation hazard than they do by oral or dermal exposure.

4. 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 file symbol 71227-R 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

LABELING:

No precautionary labeling can be prescribed until the review of the outstanding studies.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1, 870.1100)

Product Manager: 33
MRID No.: 446644-01

Reviewer: I. Blackwell
Study Completion Date: 3/23/87
Lab Project ID No.: NRILS 87-2206

Testing Laboratory : Japan Food Research Laboratory
Authors : Yasuyoshi Shimizu (K.K. Nomura Seibutsu Kagaku Kenkyusho)

Quality Assurance (40 CFR §160.12): This study was conducted according to Japan's GLPs.

Test Material: Zeomic Type AJ10D Silver Zeolite A; EPA file symbol 71227-R

Species: rats, Slc:SD strain
Age: 4 weeks
Weight: males = 122-137 g; 163-179 g
Source: Shizuoka Laboratory Animal Center

Conclusion:

1. **LD_{50} (mg/kg):** **Males > 5,000 mg/kg**
Females > 5,000 mg/kg
Combined > 5,000 mg/kg
2. **The estimated LD_{50} is greater than 5,000 mg/kg.**
3. **Tox. Category**: IV **Classification**: acceptable

Procedure (Deviations from §81-1):

Results:

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	Females	Combined
5,000 mg/kg	0/8	0/8	0/16

Observations: No abnormalities were observed.

Gross Necropsy: No abnormalities were observed.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)

Product Manager: 33
MRID No.: 446644-01

Reviewer: Ian Blackwell
Study Completion Date: 3/23/87
Lab Project ID: NRILS 87-2206

Testing Laboratory: Japan Food Research Laboratory
Author: Yasuyoshi Shimizu
Quality Assurance (40 CFR §160.12): Japanese Good Laboratory Practices

Test Material: Zeomic Type AJ10D Silver Zeolite A; EPA file symbol 71227-R

Species: rat, Slc:SD strain
Weight: males = 225-236 g; females = 164-179 g **Age**: 6 weeks
Source: Shizuoka Laboratory Animal Center

Summary:

1. **LD_{50} (mg/kg)**: **Males > 2,000 mg/kg**
   Females > 2,000 mg/kg
   Combined > 2,000 mg/kg

2. **The estimated LD_{50} is greater than 2,000 mg/kg of body weight.**

3. **Tox. Category**: III **Classification**: acceptable

Procedure (Deviation From §81-2):
☞The gauze covering the test site was not covered using an impermeable membrane (plastic).

Results:

Reported Mortality

DOSAGE	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
2,000 mg/kg	0/8	0/8	0/16

Observations: No abnormalities observed.

Gross Necropsy Findings: No abnormalities observed.

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: 33
MRID No.: 446644-02

Reviewer: Ian Blackwell
Study Completion Date: 3/2/87
Lab Project ID No.: NRILS 87-2209

Testing Laboratory: Japan Food Research Laboratory
Author: Hajime Kawasaki

Quality Assurance (40 CFR §160.12): used Japanese Good Laboratory Practices

Test Material: Zeomic Type AJ10D Silver Zeolite A; EPA file symbol 71227-R
Dosage: 0.5g (and 0.05g) on both intact and abraded sites

Species: New Zealand White rabbits
Age: ~2.5 months
Sex: not reported
Weight: 2.63-2.86 kg
Source: Shizuoka Laboratory Animal Center

Summary:

1. **Toxicity Category**: IV
2. **Classification**: acceptable

Procedure (Deviations From §81-5):

Results: No erythema, edema or other irritation was observed in any of the six test animals during the seventy-two hour observation period.

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