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

5/10/91

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: New Use Pattern for Zinc Omadine.

EPA ID# 001258-00840 Project No. 0-2013
Case No. 029309 Tox. Chem. No. 923

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John E. Whalan 4-16-91

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THRU: Roger L. Gardner, Section Head
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Roger L. Gardner 4-23-91 KB 5/10/91

I. Background:

Olin Chemicals has requested the addition of four new uses for Zinc Omadine® 40% Aqueous Solution Industrial Microbiostat (which contains 40% zinc 2-pyridinethiol-1-oxide). A letter from Olin (Garrett B. Schifilliti, April 4, 1990) described these uses as follows:

1. "For the Dry Film Preservation of Natural and Synthetic Adhesives, Caulks, Batching Compounds, Sealants, Latexes, Pastes and Grouts. Partitions, etc."

2. "For the In Can Preservation of Felts Containing Clags, Fibers, Starches, Binders, Etc. Used in Applications Such as Vinyl Flooring."

3. "To Inhibit the Growth of Bacteria and Fungi in Dry Wall and Other Gypsum, Pearlite, Plaster-like or Mineral Based Building Materials Used in the Manufacture of Ceilings, Ceiling Tiles, Walls & Partitions, etc."

4. "For Short Term Preservation of Synthetic Fiber Lubricants (spin finishes).

Supplemental labeling was provided for uses 1 through 3, but not for 4. The signal word on these labels is "Danger." No additional information was provided by the Registrant.

There are thirteen registered use patterns for zinc omadine. According to the Data Call-In Notice for Antimicrobials (William L. Burnam memorandum, March 31, 1987), all of these uses are in the Low Exposure Category except for metalworking cutting fluids which is in the High Exposure Category. The data requirements for these Categories are listed in Section III below.

Proposed new use patterns 1, 2, and 3 will result in extensive distribution in household, commercial, industrial, and institutional sites, but the product will be bound to substrates and thus will not result in undue human exposure. The Exposure Category for these uses is considered to be Low.

Proposed new use pattern 4 may result in extensive human exposure. Textile workers may receive long-term dermal exposure by handling textiles and equipment using spin processing lubricants. Furthermore, if zinc omadine is retained in cloth, the general public may also receive long-term exposure through contact with clothing. The Exposure Category for use in synthetic fiber lubricants is High.

II. Recommendation:

The data base for zinc omadine is seriously deficient. During the recent FIFRA 88 review of zinc omadine, the Registrant recognized this fact, and proposed using surrogate data for an analog - sodium omadine. This recommendation is without merit because the data base for this chemical is equally deficient. There is special concern for female workers exposed to fiber lubricants containing zinc omadine because of potential zinc-related fetal toxicity. HED cannot recommend any new uses for zinc omadine until acceptable data are available to describe its toxicologic character.

III. Data Requirements (CFR §158.35):

REGISTERED USE PATTERNS: Siding, metalworking cutting fluids, PVC plastics, PVC plastics (non-food contact surfaces), PVC tarpaulins, vinyl, shower curtains, synthetic polymers, vinyl wall coverings, vinyl coated fabrics, vinyl swimming pool liners, awnings, and tents.

Technical: Registration Nos. 1258-840, 1258-841 (purity unknown)

	Required	Satisfied	
81-1	Y	N	Acute Oral Toxicity
81-2	Y	N	Acute Dermal Toxicity
81-3	Y	N	Acute Inhalation Toxicity
81-4	Y	N	Primary Eye Irritation

81-5	Y	N	Primary Dermal Irritation
81-6	Y	N	Dermal sensitization
81-7	N		Acute Delayed Neurotoxicity (hen)
82-1	H*	N	Subchronic Oral (rodent)
82-1	N		Subchronic Oral (nonrodent)
82-2	H*	N	21-Day Dermal
82-3	L*	N	90-Day Dermal
82-4	N		21-Day Inhalation (tobacco use)
82-4	L*	N	90-Day Inhalation
82-5	N		90-Day Neurotoxicity (hen)
82-5	N		90-Day Neurotoxicity (mammal)
83-1	H*	N	Chronic Toxicity (rodent)
83-1	H*	N	Chronic Toxicity (nonrodent)
83-2	H*	N	Carcinogenicity (two species)
83-3	H,L*	N	Developmental Toxicity (first species)
83-3	H,L*	N	Developmental Toxicity (second species)
83-4	H*	N	Reproduction
83-5	N		Chronic/Carcinogenicity (see 83-1 & 83-2)
84-2	H,L*	N	Mutagenicity - Gene Mutation
84-2	H,L*	N	Mutagenicity - Structural Chrom. Aberr.
84-2	H,L*	N	Mutagenicity - Other Genotoxic Effects
85-1	H*	Y	General Metabolism
85-2	N		Dermal Penetration
86-1	N		Domestic Animal Safety

* Required studies for High Exposure Category (H) and/or Low Exposure Category (L), based on the Bill Burnam Memorandum on Data Call-In Notices for Antimicrobials (March 31, 1987).

Y - Yes
N - No
W - Waived
P - Partially

IV. Toxicology Profile:

Technical: Registration No. 1258-840, 1258-841 (purity unknown)

	STUDY	RESULTS
81-1	Acute Oral	**Data Gap**
81-2	Acute Dermal	**Data Gap**
81-3	Acute Inhalation	**Data Gap**
81-4	Primary Eye Irritation	**Data Gap**
81-5	Primary Dermal Irritation	**Data Gap**
81-6	Dermal Sensitization	**Data Gap**
82-1	3-Month Feeding, Rat **Supplementary** Document No. 3933	NOEL = 15 ppm LEL = 75 ppm (increased organ body weights for liver, kidney, and testes; decreased survival, hind limb weakness).
82-2	21-Day Dermal	**Data Gap**
82-3	90-Day Dermal	**Data Gap**
82-4	90-Day Inhalation	**Data Gap**
83-1	Chronic Feeding, Rodent	**Data Gap**
83-1	Chronic Feeding, Nonrodent	**Data Gap**
83-2	Carcinogenicity, Two species	**Data Gap**
83-3	Developmental Toxicity, Rat Invalid Document Nos. 3935, 3022	**This IBT study was invalidated.**
83-3	Developmental Toxicity (dermal), Pig Invalid Document No. 3933	**This IBT study was invalidated.**
83-3	Developmental Toxicity, Rabbit Minimum Document No. 3933	**NOTE: This IBT study is probably not acceptable because no maternal toxicity was induced at the two doses tested (1.0 and 2.5 g/kg).** Maternal NOEL >2.5 g/kg Developmental NOEL >2.5 g/kg (HDT) Reproductive NOEL >2.5 g/kg (HDT)
83-4	Reproduction	**Data Gap**
84-2	Gene Mutation	**Data Gap**

84-2	Structural Chromosome Aberration - Dominant Lethal Test, Mouse Invalid Document Nos. 3935, 3021	**This IBT study was invalidated.**
84-2	Other Genotoxic Effects	**Data Gap**
85-1	Metabolism, Pig Minimum Document No. 3933	Significant bioretention and accumulation in renal hepatic and pancreatic tissues.

V. Data Gaps:

Data requirements that have not been satisfied for High Exposure Category uses include an acute battery, subchronic feeding, 21-day dermal, chronic feeding in rodent and nonrodent, carcinogenicity in two species, developmental toxicity in two species, reproduction, and a muta-genicity battery.

Data requirements that have not been satisfied for Low Exposure Category uses include an acute battery, 90-day dermal, 90-day inhalation, developmental toxicity in two species, and a mutagenicity battery.

VI. Action Taken to Obtain Additional Information or Clarification:

These data base deficiencies were identified by the Registrant and HED in the course of FIFRA 88 review.

VII. Reference Dose (RfD):

No RfD has been defined.

VIII. Pending Regulatory Actions:

There are at this writing no pending regulatory actions against the Registration of this pesticide.

IX. Toxicologic Issues Pertinent to Granting this Request:

There are insufficient data available to allow a judgment on this petition. There is special concern for female workers exposed to fiber lubricants containing zinc omadine because of potential zinc-related fetal toxicity.