6/22/92

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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Zinc Omadine; Request for Waiver of Six Toxicology Studies.

EPA ID# 088002-001258 Project No. 2-1784
Case No. 815252 Tox. Chem. No. 923

FROM: John E. Whalan, D.A.B.T., Toxicologist
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John E Whalan 5-8-92

TO: Bruce Sidwell (PM Team # 53)
Special Review and Reregistration Division (H7508C)

THRU: Roger L. Gardner, Section Head
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Health Effects Division (H7509C)

Roger Gardner 6/17/92 KB 6/22/92

I. Background:

In response to the Phase IV reregistration Data-Call-In for Zinc Omadine, Olin Corporation has requested waivers for the following study requirements on the grounds that they are, "Not required for the existing use patterns:"

83-1a	Chronic Toxicity - Rodent
83-1b	Chronic Toxicity - Nonrodent
83-2a	Carcinogenicity - Rat
83-2b	Carcinogenicity - Mouse
83-4	2-Generation Reproduction - Rat
85-1	General Metabolism

According to the Data Call-In Notice for Antimicrobials (William L. Burnam memorandum, March 31, 1987), these data are not required for **Low** Exposure uses. They are, however, required for **High** Exposure uses.

There are currently thirteen registered use patterns for zinc omadine. All of these uses are in the Low Exposure Category except for metalworking cutting fluids which is in the High Exposure Category. Additionally, the Registrant recently proposed adding another High Exposure use pattern - Short Term Preservation of Synthetic Fiber Lubricants (spin finishes).

Data requirements for a Low Exposure Category use include an acute battery, 90-day dermal, 90-day inhalation, developmental toxicity in one species, and a mutagenicity battery. Data requirements for a High Exposure Category use 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, a mutagenicity battery, and general metabolism. These are all data gaps. A full accounting of the data base is presented in Section III below.

At the present time, the toxicology data base is not sufficient to support either the low or high-exposure uses. The Registrant has committed to conducting the two 90-day studies and developmental toxicity studies in two species.

II. Recommendation:

The HED FIRRA 88 Committee met on April 30, 1992 to discuss this petition. It appears that industrial uses for zinc omadine (e.g. metal cutting fluids and synthetic fiber lubricants) may soon cease to be under EPA's purview. Although TB-I reserves the right to request these studies once the exposure scenario is clarified, these study requirements can be waived since only low-exposure uses remain.

III. Data Requirements (CFR §158.35):

REGISTRANT: Olin Chemicals

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: Zinc Omadine (95%)
Registration Nos. 1258-840

	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	Y	Primary Eye Irritation
81-5	Y	N	Primary Dermal Irritation
81-6	Y	N	Dermal sensitization
81-7	N		Acute Delayed Neurotoxicity (hen)
82-1a	H*	N	Subchronic Oral (rodent)
82-1b	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
82-5a	N		90-Day Neurotoxicity (hen)
82-5b	N		90-Day Neurotoxicity (mammal)
83-1a	H*	N	Chronic Toxicity (rodent)
83-1b	H*	N	Chronic Toxicity (nonrodent)
83-2	H*	N	Carcinogenicity (two species)
83-3a	H,L*	N	Developmental Toxicity (first species)
83-3b	H*	N	Developmental Toxicity (second species)

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83-4	H*	N	Reproduction
83-5	N		Chronic/Carcinogenicity (see 83-1 & 83-2)
84-2a	H,L*	N	Mutagenicity - Gene Mutation
84-2b	H,L*	N	Mutagenicity - Structural Chrom. Aberr.
84-2c	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: Zinc Omadine (95%)
Registration Nos. 1258-840

	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, Rabbit **Acceptable** Document No. *?*	Ocular exposure caused severe, irreversible irritation (i.e. corrosion) which persisted for 21 days. Washing of the eye after 30 seconds of exposure was of little benefit. Rabbits with unwashed eyes were sacrificed on day 7 for humane reasons.
81-5	Primary Dermal Irritation	**Data Gap**
81-6	Dermal Sensitization	**Data Gap**

82-1a	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**
83-1a	Chronic Feeding, Rodent	**Data Gap**
83-1b	Chronic Feeding, Nonrodent	**Data Gap**
83-2	Carcinogenicity, Two species	**Data Gap**
83-3a	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.**
83-3b	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**
84-2a	Gene Mutation	**Data Gap**
84-2b	Structural Chromosome Aberration - Dominant Lethal Test, Mouse Invalid Document Nos. 3935, 3021	**This IBT study was invalidated.**
84-2c	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 mutagenicity 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 currently thirteen registered use patterns for zinc omadine. All of these uses are in the Low Exposure Category except for metalworking cutting fluids which is in the High Exposure Category.

Compiled by John E. Whalan
Revised on April 1, 1992